

## **A randomised controlled trial to evaluate the impact of a Human Rights Based Approach to dementia care in inpatient ward and care home settings**

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# **A randomised controlled trial to evaluate the impact of a Human Rights Based Approach to dementia care in inpatient ward and care home settings**

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**Keywords:** Dementia, Human Rights, training, care homes, inpatient wards, RCT

**Competing Interests:** None declared

# Abstract

**Background:** Whilst it is widely recognised that adopting a person centred approach is beneficial in dementia care there remains a gap between the rhetoric and the reality of quality care. Some widely adopted care practices can result in the personhood of this group being threatened and their Human Rights being undermined.

**Objectives:** To evaluate the impact of applying a Human Rights Based Approach (HRBA), in dementia inpatient wards and care home settings on the quality of care delivered and the wellbeing of the person living with dementia.

**Design:** A cluster randomised design was employed to compare the impact of implementing a HRBA intervention, i.e. training, 'Getting it Right' Assessment Tool, and booster sessions at 10 intervention sites as compared to 10 control sites.

**Setting:** Eight NHS dementia inpatient wards and 12 care homes in the North West of England.

**Participants:** People living with dementia who were currently residing on dementia inpatient wards or care homes. Staff working at these sites. The aim was to recruit 280 people living with dementia.

**Interventions:** A sample of staff (average 8.9 per site) at each of the sites were trained in a HRBA to care including the application of the 'Getting it Right' assessment tool. The assessment tool was then introduced at the site and monthly booster sessions delivered.

**Main Outcome Measures:** The primary outcome measure used in the research was the Quality of Life in Alzheimer's disease (QOL-AD) to assess the subjective well-being of the person with dementia. Secondary outcome measures included measures of the quality of care provided (Dementia Care Mapping) and direct measures of the effectiveness of the training in increasing knowledge of and attitudes towards human rights. The study also included an economic evaluation utilising the EQ5D-3L and the ASCOT measure.

**Results:** The study recruited 439 people living with dementia - 213 in the intervention arm of the study and 226 in the control arm. Primary outcome data was analysed using a linear

mixed model. There were no significant differences found between the reported quality of life of residents in the control and intervention groups after the intervention ( $F_{1,16.51}=3.63$ ,  $p=0.074$ ). The mean difference between groups was 1.48 [-7.86 10.82].

**Conclusions:** Despite the training increasing staff knowledge of and positive attitudes towards Human Rights, and there being some changes in staff decision making strategies in clinical situations there was no change in the quality of care provided or in the reported wellbeing of people living with dementia in these settings. This led to questions about the efficacy of training in bringing about cultural change and improving care practices.

**Limitations:** There was limited uptake of the training and booster sessions which were integral to the intervention.

**Future work:** Future work could usefully focus on understanding the difficulty in translating change in attitude and knowledge into behaviour.

**Trial Registration:** The trial was registered with the International Standard Randomised Controlled Trial Register (ISRCTN) under the reference number ISRCTN94553028

**Funding:** The project was funded by the NIHR through the HS&DR programme.

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# List of Abbreviations

AIMS	Accreditation for Inpatient Mental Health Services
ASCOT	Adult Social Care Outcomes Toolkit
BCC	Behaviour Category Code
CHOICE	Care Home Organisations Implementing Cultures of Excellence
CPA	Care Programme Approach
CRF	Case Report Forms
CSRI	Client Service Receipt Inventory
DCM	Dementia Care Mapping
DOH	Department of Health
DMEC	Data Monitoring and Ethics Committee
ENRICH	Enabling Research in Care Homes
FREDA	Fairness, Respect, Equality, Dignity, Autonomy
FRIEDA	Fairness, Respect, Identity, Equality, Dignity, Autonomy
HEE	Health Education England
HRA	Human Rights Act
HRBA	Human Rights Based Approach
HS&DR	Health Service & Delivery Research
IDEA	Identity, Dignity, Equality and Autonomy questionnaire
ISRCTN	International Standard Randomised Controlled Trial Register
ICC	Intraclass Correlation Coefficient
ITT	Intention to Treat
MCA	Mental Capacity Act
ME	Mood and Engagement Value
MLQ	Multifactor Leadership Questionnaire

MMSE	Mini Mental State Examination
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NRES	National Research Ethics Service
PPI	Patient and Public Involvement
NWORTH	North Wales Organisation for Randomised Trials in Health
QOL-AD	Quality of Life in Alzheimer's Disease Scale
RCT	Randomised Control Trial
R&D	Research and Development
SAE	Serious Adverse Events
SR	Self Report
TSC	Trial Steering Committee
WEMWBS	Warwick Edinburgh Mental Well-Being Scale
ZBI	Zarit Burden Interview

# Scientific Summary

## Background

Traditionally, people with dementia have been amongst the most devalued in our society. This has led to care practices that undermine the humanity and personhood of individuals with dementia. A Human Rights Based Approach to care establishes minimum standards of care which help to safeguard individuals, particularly those who are vulnerable. It has many overlaps with a person-centred approach but has the backbone afforded by it being a legal requirement to uphold the Human Rights of those in care. The overall aim for this study was to establish whether the application of a Human Rights Based Approach to Health Care leads to significant improvements in the care and well-being of people with dementia in hospital inpatient and care home settings. The approach chosen was an intervention developed and piloted in Mersey Care NHS Foundation Trust and involved a one day training package for staff, the implementation of the 'Getting it Right' assessment tool and booster sessions to support the implementation. The 'Getting it Right' assessment tool was a person-centred care planning tool that explicitly linked the FREDA (Fairness, Respect, Equality, Dignity and Autonomy) principles to areas contributing to person-centred care.

## Objectives

1. To investigate whether the application of a Human Rights Based Approach to Health Care, as opposed to treatment as usual, leads to significant improvements in the quality of life of people with dementia in hospital inpatient and care home settings.
2. To explore whether training on the application of a Human Rights Based Approach to Health Care leads to identifiable improvements in the quality of staff decision making.
3. To explore whether training in the application of a Human Rights Based Approach to Health Care, and the use of the Getting it Right Assessment tool, as opposed to the standard care planning procedure, leads to identifiable improvements in the person centred quality of service users' care plans.

4. To explore whether the application of a Human Rights Based Approach to Health Care leads to changes in the well-being of family carers of people with dementia who are in hospital inpatient and care home settings.
5. To validate a novel Human Rights and well-being questionnaire for dementia inpatient care based on the FREDA principles.
6. To explore the costs and consequences of embedding a Human Rights Based Approach.

## **Methods**

A cluster randomised design was employed to compare the impact of implementing the intervention, i.e. the training package, 'Getting it Right' Assessment Tool, and booster sessions at 10 intervention sites as compared to treatment as usual at 10 control sites. Eight NHS wards and 12 care homes were recruited across the North West of England. From these sites people living with dementia were recruited to complete self-report measures whenever they could give informed consent. When people were unable to give informed consent a proxy was sought. Staff members were also recruited to complete interviews which examined their decision making strategies in complex clinical situations.

### ***Inclusion/Exclusion Criteria***

Inclusion criteria were broad and are outlined below in relation to both sites (clusters) and individual participants at these sites.

- a) *Clusters* – All inpatient ward sites were NHS dementia specific wards. Care homes were included if caring for people with dementia was a part of the facilities core business and they currently had enough residents with dementia to fulfil the requirements of the study.
- b) *Individuals within clusters* – The main inclusion criteria for individuals within the cluster was a diagnosis of dementia. Issues such as age, severity of dementia, length of time at the setting were recorded but were not inclusion/ exclusion criteria in themselves. The main exclusion criterion was that an individual did not have capacity to consent and had no proxy available to support them in this.



### ***Sample size***

The sample size was based on the primary outcome measure; the QOL-AD and was based on conservative figures on several parameters; effect size (0.5) and intraclass correlation coefficient (0.05). A sample size of 10 clusters with 11 individuals per group achieves 80% power to detect an effect size of 0.5 using QOL-AD when the ICC is 0.05 using a 2 sided t-test with a significance level of 0.05. Taking a retention rate of 77% into account requires 14 participants to be recruited per cluster. This resulted in a total sample size of 280 participants. Attempts were made to recruit an informal carer for each participant living with dementia but no participants were excluded due to not having a carer. Eight members of staff from each site were interviewed about their decision making strategies in relation to complex clinical decisions.

### ***Data Collection***

Data from each site was collected at baseline then at 4 months post intervention. Every effort was made to encourage participants living with dementia to complete self-report measures but when this was not possible a proxy was sought. Initially a family carer would be approached, when one was not available a staff member could act as a proxy. In total 357 proxy measures were completed and of these 345 were completed by staff members.

### ***Outcome Measures***

The primary outcome measure used in the research was the Quality of Life in Alzheimer's disease (QOL-AD) to assess the subjective well-being of the person with dementia.

Secondary outcome measures included:

- Dementia Care Mapping (DCM) to explore quality of care provided
- A Care Plan Audit to look at the quality of care plans
- A novel FREDA based questionnaire to investigate the extent to which participants felt their Human Rights are upheld
- Staff interviews involving vignettes to explore decision making strategies

- Economic evaluation measures; ED5Q-3L, ASCOT and CSRI were completed to explore the economic impact of the evaluation and the cost of the intervention
- Human Rights knowledge and attitudes questionnaires were completed on the day of training with the intervention group and only at baseline in the control group.

In addition staff members at intervention sites were interviewed by an independent research assistant and member of the dementia PPI group about their experience of being involved in the study.

### ***Statistical Analysis***

Given that it was reasonable to assume that many participants who were involved at baseline would not be available at follow up a linear mixed model was used to assess the effect of time (baseline or follow up), group (control or intervention) and interaction of time and allocated group. Once it became evident that the ability to collect self-report data on QOL-AD was limited an additional term (self-report vs proxy) was added to the model to assess the importance of this difference.

Qualitative elements of the study; the staff decision making interviews and follow up interviews were analysed using thematic analysis.

## **Results**

The study recruited 439 people living with dementia with 213 in the intervention arm of the study and 226 in the control arm. Additionally 245 staff members were recruited to the study. There was good comparison between the groups at baseline.

### ***Primary outcome measure***

As it was found that proxy reports rated quality of life significantly lower than self-report the data from these two sources were analysed separately. There were no significant

differences found between the reported quality of life of residents in the control and intervention groups after the intervention ( $F_{1,16.51}=3.63$ ,  $p=0.074$ ).

### ***Secondary outcome measures***

There was a significant difference in both the Human Rights knowledge questionnaire ( $t(30)=-7.02$ ,  $p<0.001$ ) and the Human Rights attitudes quiz ( $t(55)=-53.87$ ,  $p<0.001$ ) demonstrating an increase in both immediately following training.

No improvements were seen in care as measured by Dementia Care Mapping (DCM). Care plan audits showed that care plans were significantly better in both control and intervention groups at follow up ( $F_{1,220.19}=22.093$ ,  $p<0.001$ ).

There were some changes in staff reported decision making strategies in the intervention group at follow up. In this group there was less reliance on 'common sense' as a way of making clinical decisions and more explicit references to Human Rights strategies and person centred care as ways of guiding decision making.

Interviews with intervention sites following the completion study highlighted that staff found the approach to be simple and of use but did not always apply it. It was found that a major factor in whether the approach was adopted or not was management support.

## **Conclusions**

The findings of this study did not support the hypothesis that increasing staff knowledge and attitudes towards Human Rights led to improvements in the care and wellbeing of people living with dementia. It does not of course imply that the issues of Human Rights are not important for this group of people. People at later stages of dementia remain some of the most vulnerable in our society and unfortunately reports of Human Rights abuses continue. There remains a need to find a way to ensure that the Human Rights of people with dementia are both respected and promoted.

The study highlighted some of the difficulties that exist within health and social care systems. The care and support that people received was inconsistent and failed to meet the standards we might expect for some of the most vulnerable in our society. Person-centred care was not routine and there were many examples of institutionalised behaviours. Human Rights were concepts that were alien to staff and were not routinely considered when providing care. Staff did not feel empowered to act independently to support the people at their units and the management support that was provided was variable. In order to provide quality care that is person centred and respectful of the Rights of people with dementia it is essential that the cultures care is delivered in are suitable. The results of this study taken together give some indications of factors that may influence the development of these cultures of care. These include:

- Managers who lead and are willing to adopt an innovative approach to change
- All staff feeling empowered to make decisions and to act in ways that they see as appropriate.
- A shift away from training that has awareness raising as its only aim
- A tolerance of risk
- Full involvement of service users in service development and delivery
- Entire sites adopting new cultures
- Monitor progress in relation to Human Rights based targets

These factors link well with the PANEL principles which form the basis for a Human Rights Based Approach to care. They encourage active participation of all stakeholders including managers, staff and service users. They highlight the importance of all levels of staff being accountable for their own actions as opposed to always deferring to more senior colleagues. They actively promote the voices of vulnerable groups, in this case people living with dementia, in ensuring practices are non-discriminatory. They seek to empower all staff regardless of grade and to empower service users to take control of their own services and they provide a clear framework through adherence to Human Rights principle to ensure that all decisions taken are legal.

### ***Implications for Health Care***

The study highlights a number of implications for health care both in the way that it is currently provided and in relation to future planning. The study highlights that training alone in a traditional format is potentially not a good medium for bringing about cultural change. Instead training must embrace models that allow learners to understand the material, apply it to their own work and feel that this is making a difference to the wider organisation. Whilst this method of training may be more time consuming and initially more expensive it may limit the dangers of training and retraining with no notable difference to service delivery.

The findings also suggested that the management of services is of vital importance when implementing a new initiative. For this reason managers should be chosen who have values congruent with that of the direction the organisation wishes to move in.

It was noted that care plans improved in both groups at follow up implying that monitoring improved their quality. It may be that monitoring services against explicitly Human Rights based standards may improve the quality of services provided.

### ***Future Research Implications***

A major concern raised by the study was the effectiveness of current outcome measures in capturing meaningful change in dementia. A research priority should be the development of more appropriate and dementia sensitive tools to measure outcomes related to quality of life and wellbeing.

At the outset this study worked from the premise that the Human Rights of people living with dementia would be the same as everyone else due to the nature of Human Rights being fundamental principles which apply simply because we are human beings. Public engagement throughout the course of the study however highlighted that the understanding of Rights when dementia is involved may be subtly different. One area that consistently arose was the centrality of identity in preserving and promoting the rights of people living

with dementia. Similarly, there were numerous fascinating debates in the sessions related to the changing nature of autonomy and the relative importance, or not of individual autonomy as a concept. These are both areas which could warrant further research to investigate their role in quality of life and well-being of people living with dementia.

## **Patient & Public Involvement**

In line with the ethos of the study, i.e. maintaining and promoting the Human Rights of those with dementia, people living with dementia and people supporting them were involved in all aspects of the study including; the design of the Getting it Right assessment tool and FREDA questionnaire, as members of the Trial Steering Committee, through work of the wider reference group and as interviewers post intervention.

The reference group have been working on ways to ensure that the Rights of people living with dementia are promoted more widely. To this end they are producing a short film based on the practical application of a Human Rights Based Approach to dementia care.

## **Trial registration**

The trial was registered with the International Standard Randomised Controlled Trial Register (ISRCTN) under the reference number ISRCTN94553028

## **Funding**

The project was funded by the NIHR through the HS&DR programme.

**Word Count: 2314**

## Plain English Summary

This study aimed to explore whether training staff to use a new assessment tool called 'Getting it Right' could improve the quality of care provided in dementia specific NHS wards and care homes. The assessment tool was based on Human Rights principles and explicitly linked person-centred care to the Human Rights FREDa (Fairness, Respect, Equality, Dignity and Autonomy) principles. The assessment tool and training was designed by and piloted at Mersey Care NHS Foundation Trust. Staff members completed the assessment tool with residents on their unit and were offered booster consultation sessions to help them with any problems they encountered completing it.

Twenty sites were recruited to the study across the North West of England (12 care homes and 8 NHS wards). These sites either received the intervention package described above; training, applying the 'Getting it Right' assessment tool and booster sessions, or continued with care as usual. Measures were completed before the study began and after 4 months to see whether there were any differences in relation to the well-being of people living with dementia and the quality of care provided. Staff members were also interviewed to look at whether the way they made decisions changed.

It was found that whilst there were improvements in staff knowledge about Human Rights following the training, and staff expressed more positive attitudes towards Human Rights there were no improvements in the care provided or in the well-being of people living with dementia. Staff also reported different decision making strategies following the intervention.

Whilst staff generally reported that the approach was simple and easy to use there was evidence of it not having been routinely used. Interviews showed that management support was important in whether the approach was applied. Future research could focus on different ways of ensure people apply new initiatives.

**Word Count: 299**

# Chapter 1 - Introduction

## Scientific Background

### *Dementia in Society*

There are currently over 850,000 people living with a diagnosis of dementia in the UK <sup>[1]</sup>. As well as the biological changes associated with a dementia process, which can lead to a range of cognitive difficulties, dementia is also associated with numerous psychological and social consequences. 61% of people living with dementia have reported feeling anxious or depressed, 40% reported feeling lonely and just over a third did not feel a part of their community <sup>[1]</sup>. This poses a major threat to the quality of life for a large number of people in our society and is in direct conflict with the National Dementia Strategy which aimed to help people with dementia to 'live well with dementia' <sup>[2]</sup>. It is estimated that the cost of dementia to the UK each year is £26 billion <sup>[3]</sup>. We live in an ageing population and the issues associated with dementia will continue to increase. The status quo is unsustainable. Providing good quality care to people with dementia is an issue that will continue to be a concern over the coming years.

In 2007 the Alzheimer's society published Dementia UK <sup>[4]</sup>, in this report they stated "Dementia must be made a publicly stated national health and social care priority. This must be reflected in plans for service development and public spending". In 2009 The National Dementia Strategy was published outlining the government's plan for providing quality services in dementia care <sup>[2]</sup>. Dementia has been highlighted as a Government priority. The Prime Minister launched a programme of work which aims to deliver major improvements in dementia care and research by 2020. This focused on improving the service provided for people with dementia so that England is the best country in the world for dementia care and support and for people with dementia and the carers and families to live <sup>[5]</sup>. It also focuses on ensuring that England is the best place in the world to undertake research into dementia.



Dementia is widely feared in society <sup>[6]</sup> and traditionally people with dementia have been the most devalued in our society experiencing the double stigma of old age and cognitive impairment. Kitwood suggested that personhood (i.e. the state of being a person) is bestowed on us by the treatment of others <sup>[7]</sup>. The stigma and misperceptions surrounding dementia and the resulting reactions by people towards those living with dementia have led to care practices that can undermine the humanity and personhood of an individual with dementia <sup>[7]</sup>. The literature highlights issues such as removing all choice and personal autonomy from people with dementia <sup>[8]</sup>, restraint and restrictions on 'wandering'. It is clear that there are occasions when human rights for people with dementia are unnecessarily limited and their application is not routinely considered in clinical decision making <sup>[9]</sup>. It is essential that approaches are adopted which maintain the humanity of an individual and challenge the stigma associated with dementia that people often report feeling.

### ***Human Rights***

Human Rights are brought into UK law through the Human Rights Act <sup>[10]</sup>. They represent the fundamental ways in which a person can expect to be treated simply by virtue of being a human being. Although they are based on values held for centuries they became formalised following the atrocities of the Second World War, in particular the Holocaust. It was acknowledged that human beings can inflict dreadful suffering on other individuals and explicit statements on our rights as human citizens were required. The articles of the Human Rights Act are broad ranging; covering physical, psychological and social issues. They represent the minimum standard of treatment that we should expect. The articles of the Human Rights Act are outlined in Table 1.

The United Nations adopted the Universal Declaration of Human Rights in 1948 <sup>[11]</sup>. The European Convention on Human Rights <sup>[12]</sup>, created in 1950 by the Council of Europe, was the first post-war attempt to unify Europe and institutionalise the shared values of democracy, human rights and the rule of law. The UK was among the first states to ratify the Convention and British jurists were highly influential in its design. The Human Rights Act

incorporates most of the Convention rights into UK law. It came into force across the UK in October 2000.

**Table 1:** The Articles of the Human Rights Act

<b>Part I:</b>	<b>The convention rights and freedoms</b>
Article 2:	The right to life
Article 3:	The right not to be tortured or treated in an inhuman or degrading way
Article 4:	The right to be free from slavery or forced labour
Article 5:	The right to liberty and security
Article 6:	The right to a fair trial
Article 7:	The right to no punishment without law
Article 8:	The right to respect for private and family life, home and correspondence
Article 9:	The right to freedom of thought, conscience and religion
Article 10:	The right to freedom of expression
Article 11:	The right to freedom of assembly and association
Article 12:	The right to marry and found a family
Article 14 :	The right not to be discriminated against in relation to any of the rights contained in the European Convention
Protocol 1: Article 1:	The right to peaceful enjoyment of possessions
Protocol 1: Article 2:	The right to education
Protocol 1: Article 3:	The right to free elections
Protocol 13: Article 1:	Abolition of the death penalty

Human rights law, including the rights included in the Human Rights Act can be understood through the FREDA principles <sup>[13]</sup>. The FREDA principles are not law in and of themselves. They are the values which run through the rights protected by the Human Rights Act and are at the heart of high quality health and social care. The FREDA Principles are: Fairness, Respect, Equality, Dignity, and Autonomy.

## **Human Rights in Health Care**

*“Where, after all, do human rights begin? In small places, close to home – so close and so small that they cannot be seen on any map of the world. Yet they are the world of the individual person....”*

*(Eleanor Roosevelt, 1958)*

Human Rights are diagnosis neutral and compel us to treat everyone as human beings regardless of the difficulties they may be experiencing. They also recognise however that in certain complex cases, a balance may need to be struck in order to meet competing rights of different individuals or to protect an individual from unwarranted risk, and rights may need to be limited. A Human Rights Based Approach describes the process of using the articles of the Human Rights Act in a very practical way to influence daily life <sup>[14]</sup>. A Human Rights Approach to care both allows for that balance to be considered and provides a lens through which such difficult decisions can be made. Failure to take the Human Rights of the service user into account can also lead to legal suits which impose an additional financial burden and undermine public confidence in services <sup>[15, 16]</sup>. The National Health Service Constitution states that the NHS ‘has a duty to each and every individual that it serves and must respect their human rights’ <sup>[17]</sup>.

It is not only unlawful for NHS organisations to work in a way that is incompatible with Human Rights but the application of a Human Rights Based Approach establishes minimum standards of care which help to safeguard individuals, particularly those who are vulnerable. They also remind us that individuals require a great deal more than safeguarding in order to maintain their self-respect and sense of dignity. The culture of organisations has led, on occasions, to staff delivering task orientated, risk averse, care that fails to consider the human rights of an individual <sup>[15]</sup>. Human Rights, in this context, can therefore be viewed as codifications of how relationships can be understood and the social obligations we hold as human beings <sup>[18]</sup>.

The Human Rights Act <sup>[10]</sup> is law; however within healthcare settings, it needs translating into a clear set of principles that guide everyday practice bridging the gap between the legal system and good quality health care <sup>[19]</sup>. The Human Rights in Healthcare document <sup>[20]</sup> achieves this translation by outlining the key ingredients of a Human Rights Based Approach. An alternative but similar construction is found within the PANEL principles <sup>[8]</sup>. The PANEL principles are participation, accountability, non-discriminatory, empowerment and legality, and they are defined more fully in Table 2. They represent guiding principles for organisations to follow to maximise the chances of the services they deliver aligning to a Human Rights Based Approach.

**Table 2:** Explanation of the PANEL Principles in Health Care Settings

PANEL Principle	Description
Participation	To ensure that all stakeholders are meaningfully engaged in the service
Accountability	To ensure there is clear accountability and transparency to services being provided
Non-discriminatory	To ensure that particular attention is paid to vulnerable groups
Empowerment	To ensure empowerment of all stakeholder groups
Legality	Looking at things through a Human Rights lens and ensuring all action taken are legal

Making the link between law and ethical practice is not the only step required; there is also a need to translate the concepts in a Human Rights Based Approach into practical strategies to facilitate the everyday decision making of staff. In other words to make ‘choices guided by values’ <sup>[21]</sup> and guided by the more practical elements of a HRBA such as proportionality (i.e. responding to situations in a way that is appropriate in magnitude and degree), fit with other legal frameworks such as the Mental Health Act and Mental Capacity Act, proactive strategies (predicting responses to events through knowledge of the person and responding prior to a negative event) and balancing rights and risks to make sensible decisions.

### ***The Disability Model of Dementia***

Discussions around dementia and the difficulties it causes to individuals have historically been dominated by a medicalised notion of dementia; where there is no cure and nothing can be done other than watch the person decline <sup>[22]</sup>. More recent social movements to recognise dementia as a disability <sup>[23]</sup> have opened up opportunities to frame dementia within a rights based approach. The United Nations convention on the rights of persons with Disabilities (CRPD) <sup>[24]</sup> aims to ensure that there is ultimately no discrimination towards people living with a disability and that their Rights are maintained and promoted. The UK has ratified the CRPD meaning that all UK laws and policies should be compliant with it <sup>[25]</sup>. As a result people living with dementia should be able to utilise the CRPD as a way of protecting and promoting their Rights.

### ***Human Rights and Dementia***

Whilst there is still limited empirical work done specifically in the area of dementia and Human Rights, the last few years have seen an expansion of this topic as an area of focus. Several Charters of Human Rights have been produced <sup>[26, 27]</sup> aiming to influence policy related to dementia. Literature also exists considering some of the major issues that may threaten an individual's human rights. Laird <sup>[28]</sup> provided examples of how fundamental human rights can be violated in health care settings – “situations cited by British Institute of Human Rights include failure to change soiled bed sheets, neglect leading to pressure ulcer development, not helping people to eat when they are too frail to eat themselves, excessive force used to restrain people and washing or dressing people without regard to dignity” (P.6).

It is notable however, that the majority of publications are focused at a policy level <sup>[29]</sup> or are discussion papers reviewing a concept <sup>[30]</sup> as opposed to attempts to apply a Human Rights Based Approach in practice and evaluate its effectiveness. In 2016 Dementia Alliance International launched ‘The Human Rights of People Living with Dementia: from Rhetoric to Reality’ <sup>[31]</sup>. Whilst this is a move to ensure that people living with dementia are aware of their Rights it still stops short of outlining specific applications of a Human Rights Based Approach. The Dementia Engagement and Empowerment Project (DEEP) have worked

alongside people with dementia to produce 'Our Dementia, Our Rights'<sup>[32]</sup>. Whilst this is a real attempt to raise the issue of Rights in the collective minds of society and produce a document in an accessible format it stops short of making very practical recommendations of how Human Rights law can influence the day to day lives of people living with dementia.

Since the work of Tom Kitwood<sup>[7]</sup> it has been widely accepted that Person Centred principles are important in providing high quality dementia care. They have however been criticised for being vague and difficult to research and enforce<sup>[33]</sup>. There are high levels of congruence between the fundamental principles of person centred care and a Human Rights Based Approach such as empowerment and inclusion<sup>[34]</sup>. A Human Rights Based Approach gives backbone and a legal framework to person centred principles<sup>[34]</sup> potentially making them clearer to operationalise and more accessible to rigorous research.

### ***Human Rights Training***

Although there are various models of training to promote human rights awareness<sup>[35]</sup>, there is limited evidence for their efficacy in terms of behavioural change<sup>[36]</sup>. These models include:

- Values and Awareness model – this model focuses on transmitting basic knowledge of human rights.
- Accountability model – this model assumes that participants will already be involved in the protection of individual and group rights and focuses on professional responsibility in relation to this.
- Transformational model – this model is geared towards empowering individuals who have previously experienced human rights abuses to both recognise human rights abuses and commit to their prevention.

The suggested common themes amongst these models is fostering and enhancing leadership, coalition and alliance development and personal empowerment<sup>[35]</sup>.

Attitudinal change for staff through human rights awareness training may be more effective where staff's emotional responses, defences and the impact of organisational culture are emphasised<sup>[36]</sup>. Reflections on rights awareness training in both dementia and Intellectual

Disabilities services suggests change might be achieved through placing ethical decision-making centrally. This has been termed 'dilemma-based learning' <sup>[34]</sup>.

## **Human Rights Evaluation**

The need to evaluate human rights initiatives is often overlooked and there is no real consensus about *how* to evaluate <sup>[37]</sup>. It has been argued that the evaluation of Human Rights Based Approach is problematic for a number of reasons including; a belief that legal concepts should be monitored rather than evaluated, a fear that evaluation will lead to legal ramifications and a distaste for quantifying the extent of human misery and abuse where rights are not being upheld <sup>[34]</sup>.

Donald <sup>[37]</sup> provides a clear framework for evaluating HRBA in healthcare services. This framework encourages the exploration of human rights knowledge and understanding, skills in applying HRBA, attitudes, perspectives and values and ultimately the outcome and impact of applying the approach for the realisation of human rights. There is an argument that this is more palatable, as it allows researchers to directly assess the process and impact of the HRBA rather than attempting to quantify abuses.

## **Rationale for research**

### ***Cultures of Care***

It may be comforting to assume that the Human Rights of the most vulnerable people in our society are routinely upheld and promoted by those tasked with caring for them. Unfortunately the sad truth is that this is not always true. The Francis report <sup>[38]</sup> arising from the lack of care provided at Mid-Staffordshire NHS Foundation Trust highlighted the importance of creating the 'right culture of care' to ensure that people are treated in ways that promote dignity and respect.

The Care Quality Commission routinely uncovers practices threatens the Human Rights of people living with dementia. For example, in one care home inspectors noted many people

remained in bed all day with no rationale behind this behaviour. When they questioned staff on this they were told; *'One side [of the house] we get up Monday, Wednesday and Friday. The other side we get up Tuesday, Thursday, Saturday'* <sup>[39]</sup>. This is obviously completely unacceptable and in direct conflict with the principles of the Human Rights Act.

When considering the moral imperative we all hold to protect the vulnerable it has been highlighted that 'compassion is the basis for all morality' <sup>[40]</sup>. If we wish to develop cultures of care where person centred care is a reality then it has been suggested that 'the NHS must be a fertile soil for meaningful caring relationships' <sup>[41]</sup>. The work of Martin Buber <sup>[42]</sup> encouraged viewing relationships as 'I-Thou', thereby engaging on a human to human level with the people we provide care and support for, as opposed to 'I-It' which adopts a detached task-orientated approach whereby people are viewed as jobs to be done and tasks to be completed. It has been suggested that in many care setting 'the gap between the rhetoric and the reality remains uncomfortably wide' when we are considering models of person centred care <sup>[43]</sup>. There is no obligation to carry out person centred care other than knowing it is the right thing to do. With their statutory weight, Human Rights approaches can strengthen person-centred approaches <sup>[44]</sup> and maximise the chances of them being adopted.

### ***Training and Care***

The training currently provided to care providers does not automatically feel congruent with the aim of producing compassionate, person centred cultures of care. It is recognised that there are major failings in the training of staff who provide care, particularly those who work in the care home sector. The Care Quality Commission (CQC) found that of those care homes told to improve after a visit 71% had significant training gaps with dementia care, safeguarding and the Mental Capacity Act faring worst <sup>[45]</sup>. This is particularly worrying given that over 70% of people who are residents of care homes are living with dementia <sup>[1]</sup> and by the virtue of residing in a care home there is likelihood that there will be queries over capacity.



In providing training we are assuming that we are equipping people to make complex clinical decisions on a day to day basis. In reality we are often training people to become task orientated and driven. Models of training which include real life situations tend to produce better outcomes with more emotional attachment to them <sup>[34]</sup>.

### ***Care Planning***

The availability of a good quality person centred care plan does not automatically ensure that good quality person centred care is provided but it does provide a template by which the standard of care can be judged. NHS England (2017) state that, 'care planning is a crucial element in delivering improved care for people living with dementia' <sup>[46]</sup>. NICE <sup>[47]</sup> quality standard 4 for dementia requires that each person has a personalised care plan. There are models of good quality care planning e.g. Enhanced care planning but these are often not adopted. Traditional care planning approaches adopted in NHS services e.g. the Care Programme Approach (CPA) do not always lend themselves to the full involvement of people living with dementia due to the somewhat restrictive nature of their content and a focus on risk assessment <sup>[48]</sup>. It has been suggested that the CPA maintains 'a system which too often defines people by their diagnosis and medication' and 'finds it difficult to recognise the whole person and the unique individual' <sup>[49]</sup>. Any model of quality dementia care recognises the centrality and importance of an in-depth knowledge of the person, their wishes, and preferences in providing support that is person centred and therefore upholds their Human Rights <sup>[50]</sup>. It therefore follows that a good quality care plan should be a vehicle for collating this detailed knowledge about a person and their care.

### ***Decision Making in Care Settings***

It is recognised that "making decisions that concern people's health and quality of life creates complex ethical dilemmas, and one has to choose among alternatives" <sup>[51]</sup>. This can lead to decisions which have an impact on an individual's human rights. For example, Robinson et al <sup>[9]</sup> explored the area of balancing risks and rights in relation to wandering. They highlighted that staff often act in particular ways, such as having a locked door policy, through fear of being viewed as negligent. The implementation of a Human Rights Based Approach may provide staff with a more comprehensive and robust framework in which

decision can be made drawing on the human rights principles, particularly proportionality, least restrictive practice and proactive strategies rather than relying on the most risk adverse approach <sup>[34]</sup>.

### ***Rationale***

We are existing in systems where the care provided to some of the most vulnerable people in society is failing to meet their complex needs. Additionally we are not equipping our workforces to meet these needs through woeful lack of investment in their development.

This project will build on the existing literature exploring how the Human Rights of people living with dementia can be undermined and unnecessarily restricted within traditional models of care but expand the focus to look at an operationalised model of providing care that embeds a Human Rights Based Approach. The proposed intervention aimed to put Human Rights at the heart of care planning and service delivery. A Human Rights Based Approach was chosen as the appropriate focus for this project because, not only does the NHS have a legal requirement to uphold the Human Rights of service users, but it is recognised that quality care is both person centred and respectful of an individual's Human Rights <sup>[52]</sup>.

Embedding a Human Rights Based Approach through the application of the Getting it Right Assessment Tool and training package aimed to maximise quality of life and well-being for people with dementia and provide a framework for staff to make decisions about care within a Human Rights Based Approach, using the principles of proportionality, proactive strategies, positive risk taking and use of least restrictive practices.

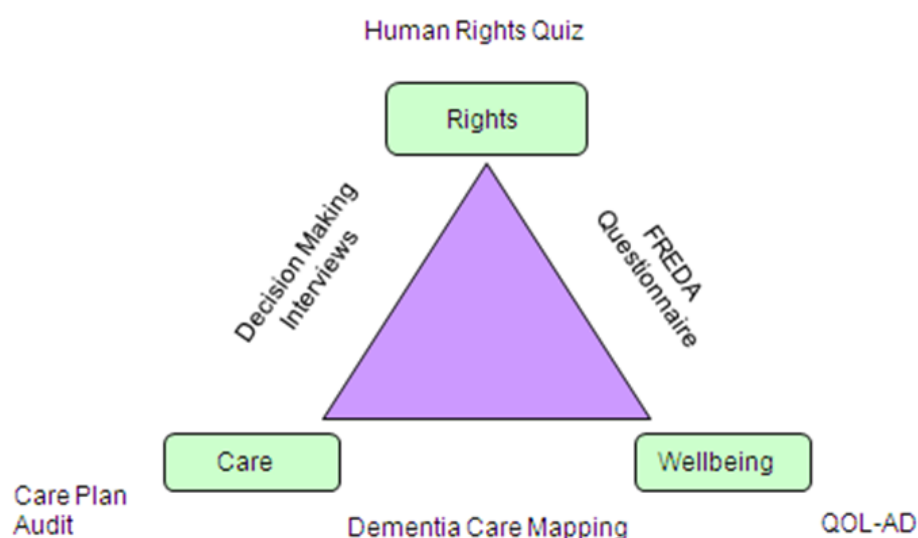
### **Conceptual Framework**

The underlying conceptual framework for the study was that the introduction of a Human Rights Based Approach to health care would lead to improvements in the well-being of people with dementia and the care they receive. This is summarised in figure 1 below and highlights how the outcome measures used allowed the exploration of these areas and the links between them. Specifically, the QOL-AD <sup>[53]</sup> allowed measurement of changes in

subjective well-being but would not explain why these changes had taken place. The care plan audit measured the documented standard of care that a person should be receiving and also tapped into increases in Human Rights based language etc. which would be suggestive of the Human Rights Based nature of the intervention having an effect over and above simply providing generic training. Care plans do not however capture the actual care that is delivered and how it affects well-being. Dementia Care Mapping was used to explore whether care provided on a unit changed and the effect this had on well-being of service users on the unit.

The completion of Human Rights knowledge and attitude quizzes measured changes in these areas pre and post training but does not look at the impact this has on staff in their everyday working lives and how it affects service user well-being. Staff interviews were conducted to explore whether the introduction of a Human Rights Based Approach leads to differences in decision making processes when considering care issues. Similarly the FREDA based questionnaire was included to allow the team to explore whether service users are feeling that their Human Rights are respected more after the intervention.

**Figure 1:** Conceptual framework for the study



## **Aims and Objectives**

**Aim:** To establish whether the application of a Human Rights Based Approach to Health Care leads to significant improvements in the care and well-being of people with dementia in hospital inpatient and care home settings.

### ***Specific Objectives:***

1. To investigate whether the application of a Human Rights Based Approach to Health Care, as opposed to treatment as usual, leads to significant improvements in the quality of life of people with dementia in hospital inpatient and care home settings, as measured by scores on the QOL-AD.
2. To explore whether training on the application of a Human Rights Based Approach to Health Care leads to identifiable improvements in the quality of staff decision making as measured by vignette-based interviews with staff.
3. To explore whether training in the application of a Human Rights Based Approach to Health Care, and the use of the 'Getting it Right' Assessment tool, as opposed to the standard care planning procedure, leads to identifiable improvements in the person centred quality of service users' care plans as measured by care plan audits.
4. To explore whether the application of a Human Rights Based Approach to Health Care leads to changes in the well being of family carers of people with dementia who are in hospital inpatient and care home settings, as measured by the Warwick Edinburgh Mental Well-Being Scale <sup>[54]</sup> and the Zarit Burden Interview (ZBI) <sup>[55]</sup>.
5. To validate a novel Human Rights and well-being questionnaire for dementia inpatient care.
6. To explore the costs and consequences of Human Rights training for staff looking after people with dementia in a hospital and care home setting in terms of patient reported well-being, care plan development, staff stress, family member well-being and overall quality of care, as compared to usual patient management.

# Chapter 2 - Trial Design and Methods

## Study Design

The study was designed to evaluate whether the application of a novel Human Rights based intervention could improve the standard of care delivered in dementia inpatient wards and care home settings as opposed to treatment as usual.

The research employed a cluster randomised design to compare the impact of implementing the intervention, i.e. the training package, 'Getting it Right' Assessment Tool, and booster sessions at 10 intervention sites as compared to 10 control sites. The control sites continued with treatment as usual. No active placebo was indicated. It was acknowledged that there may have been significant variation in what constitutes treatment as usual across the sites involved in the study.

Data collection points were at baseline (see randomisation) and at 4 months post intervention. Training was delivered at the intervention sites and booster sessions were given for a 3 month period post-training.

## Intervention Package

The intervention package being applied was a novel Human Rights Based intervention package that had previously been piloted within the host Trust (Mersey Care NHS Foundation Trust). It consisted of three linked elements:

1. A one day training package delivered to staff from the intervention unit at a time and place that was convenient to the site. The training was delivered by co-applicant Dr Sarah Butchard who jointly developed the intervention package and is an experienced Clinical Psychologist and Senior Clinical Teacher. It was based on dilemma based learning; utilising clinical scenarios that common occur in dementia services. It incorporated both direct learning about a Human Rights Based Approach

and its utility in dementia as well as the practical application of the Human Rights Based Assessment Tool (Getting it Right).

2. The completion of a Human Rights Based assessment tool, 'Getting it Right' (Appendix 1) which was based on person centred principles and on the learning from Enhanced Care Planning (Hazel et al). The aim of the tool was to build up a person centred care plan which was explicitly linked to the FREDA principles. Each unit was given a set of the assessment tools following the training and requested to complete the assessment with both new and existing residents on the unit. There was no stipulation made of how many assessments needed to be completed at each unit. It was emphasised that any member of staff, not just qualified members, could complete the assessment with residents and it was more important that it was completed by someone who had a good relationship with that person.
3. Monthly booster sessions were delivered by Dr Sarah Butchard to address issues arising from the application of the 'Getting it Right' assessment tool. Three booster sessions were offered – one per month over the three months following the training. These adopted a consultation model and allowed staff to reflect on any difficulties with applying the assessment tool.

## **Ethical Approval and Research Governance**

A protocol was submitted for ethical consideration to the National Research Ethics Service (NRES) committee North West – Haydock (ref: 14/NW/1117) in June 2014 and it was approved in August 2014. No requests for alterations were made prior to approval being granted. For participating NHS sites approval was also sought from the relevant NHS Trust research and development (R&D) departments.

The trial was registered with the International Standard Randomised Controlled Trial Register (ISRCTN) under the reference number ISRCTN94553028 (<http://www.isrctn.com/ISRCTN94553028>).

## **Patient and Public Involvement**

Ensuring that people living with dementia were meaningfully involved in all aspects of the study was seen as essential due to its congruence with the key aims of the project; to ensure dignity and respect whilst remembering that the individuality of human needs does not diminish with the passage of time or diagnosis.

People living with dementia and carers were included in all stages of the study. People with dementia and carers were fully involved in the development of both the Getting it Right Assessment Tool and FREDA based questionnaire (IDEA) through a series of focus groups and consultation exercises.

Two people living with dementia and a carer were key members of the Trial Steering Committee and contributed fully to these meetings throughout the duration of the study advising on the smooth, ethical running of the study.

Alongside this, a PPI reference group was set up including service users, carers and other interested stakeholders. This group worked on the wider issues impacting on, and evolving from the research such as the perception of Human Rights amongst people living with dementia.

People living with dementia and carers also co-facilitated the interviews with staff that had completed training at sites following the completion of the study to look at acceptability.

The group was consulted about the results of the study and their comments are incorporated into the discussion.

## **Participants**

The populations to be investigated during this study were people living with dementia, their carers and staff of NHS inpatient dementia wards and care homes. All people living with dementia were either existing residents or new admissions to the dementia care units. Carers in this context referred to family members, or significant others, of the people living

with dementia. People living with dementia did not have to have a carer in order to be involved in the study.

### ***Inclusion/Exclusion Criteria***

Inclusion criteria were broad and are outlined below in relation to both sites (clusters) and individual participants at these sites.

- a) *Clusters* – All inpatient ward sites were NHS dementia specific wards. Care homes were included if caring for people with dementia was a part of the facility's core business and they currently had enough residents with dementia to fulfil the requirements of the study.
- b) *Individuals within clusters* – The main inclusion criteria for individuals within the cluster was a diagnosis of dementia. Issues such as age, severity of dementia, length of time at the setting were recorded but were not inclusion/ exclusion criteria in themselves. The main exclusion criterion was that an individual did not have capacity to consent and had no proxy available to support them in this.

### ***Setting***

The research was conducted in dementia inpatient wards within NHS Trusts and care homes. Table 3 shows the sites who participated in the study and the basic characteristics of these sites.

Although the initial aim was to recruit 10 NHS wards and 10 care homes practicalities resulted in 12 care homes and 8 NHS wards being recruited. In reality however far more people living with dementia are care home residents than are admitted to specialist dementia wards. It is estimated that a third of people with dementia live in care homes <sup>[57]</sup>. It is harder to obtain specific figures related to those accessing specialist dementia wards but figures for the local regions where the study was carried out suggest that only 1.5% of people living with dementia will need support on a specialist dementia inpatient ward <sup>[58]</sup>. It is therefore reasonable that more care homes than wards were included if the figures are to represent the population of people living with dementia.



**Table 3:** Characteristics of the sites involved in the study

Site	NHS Ward or Care Home	Intervention or Control	Number of beds	Total number of staff	Number of day staff	Average number of staff on shift
<b>Dale Park</b>	Care home	Intervention	44	38	38	7
<b>Redholme</b>	Care home	Control	55	47	35	9
<b>Abbottsburys</b>	Care home	Intervention	20	23	19	5
<b>Finch Manor</b>	Care home	Intervention	89	85	51	18
<b>Avalon</b>	Care home	Control	20	31	19	5
<b>Acacia Court</b>	Care home	Control	26	16	16	5
<b>Irwell Ward</b>	NHS Trust	Control	17	43	33	6
<b>Meadowbank Ward</b>	NHS Trust	Intervention	13	45	23	9
<b>Tudorbank</b>	Care Home	Control	46	34	24	7
<b>Greeacres</b>	Care Home	Intervention	41	38	20	5
<b>Cherry Ward</b>	NHS Trust	Intervention	11	37	23	8
<b>Whiston &amp; Halton Wards</b>	NHS Trust	Control	20	50	35	6
<b>Leigh Ward</b>	NHS Trust	Control	23	36	24	6
<b>Hollins Park</b>	NHS Trust	Intervention	18	32	21	6
<b>Larkhill Hall</b>	Care home	Intervention	66	63	37	11
<b>Cressington Court</b>	Care home	Control	56	59	32	9
<b>Macclesfield</b>	NHS Trust	Intervention	15	47	43	7
<b>The Harbour</b>	NHS Trust	Control	36	91	73	10
<b>Thomas Leigh</b>	Care home	Control	19	40	13	4
<b>St Luke's</b>	Care home	Intervention	56	78	51	22

### ***Sample Size***

The sample size was based on the primary outcome measure, the QOL-AD <sup>[53]</sup>, and was based on conservative figures on several parameters.

*Effect size*- The literature indicated that previous similar research yielded effects sizes of 0.6 <sup>[59]</sup>. It is necessary to be more conservative given practical experience, hence an effect size of 0.5 was used when calculating the sample size.

*Intraclass correlation coefficient (ICC)* - Other trials utilising the QOL-AD have applied an ICC of 0.02 based on pilot work <sup>[60]</sup>. As this was a different intervention and the differences between groups/clusters was the important aspect we chose to apply a more conservative ICC of 0.05.

*Sample size* – The sample size was calculated based on detecting an effect size of 0.5 in the QOL-AD using a 2-sided t-test. In order to achieve 80% power with a significance level of 0.05, and an ICC of 0.05, a sample size of 10 clusters with 11 individuals per group was required. Based on prior research a retention rate of 77% <sup>[61]</sup> was accounted for, which required a sample size of 10 clusters with 14 individuals per group. This results in a total sample size of 280 participants.

Family carer well-being was explored via the WEMWBS <sup>[54]</sup>. The study aimed to recruit a family care giver for each participant but acknowledged that in reality this would not be possible. The sample size for this group was therefore dictated by the number of participants who had a family carer willing to take part in the trial. Staff vignette based interviews were developed to explore decision making strategies employed. The aim was to recruit 50% of staff per site. Similarly, as the care plan audit has been designed specifically for this trial a more pragmatic approach to sample size was taken. A sample of 50 % of all care plans at a particular site was taken.

### ***Recruitment Procedure***

Initial expressions of interest to be involved in the study were invited from local NHS Trusts and care homes via existing networks and contacts. A decision was made to recruit initially within the North West of England due to logistical and financial constraints.

The research team also worked closely with the NIHR ENRICH (Enabling Research in Care Homes) programme to identify care homes that identified themselves as being willing to participate in research and to support care homes in being involved in the study. Initially all care homes in the North West area who had been identified as being research ready were approached and invited to take part in the study.

### Characteristics of sites

The sites recruited varied in terms of their size, current levels of occupation and percentage of residents living with dementia. Table 4 outlines these characteristics at both baseline and follow up time points. It is evident from these figures that even if the care homes were not branded as exclusively for people living with dementia a high proportion of residents were living with this condition.

**Table 4:** Characteristics of participating sites at baseline and follow up

Site	Timepoint	Number of beds	Number of service users	Number of service users with dementia
Redholme	Baseline	55	48	48
	Follow-up	55	50	50
Irwell Ward	Baseline	17	13	12
	Follow-up	17	12	11
Dale Park	Baseline	44	42	41
	Follow-up	44	42	41
Accacia Court	Baseline	26	23	23
	Follow-up	26	24	24
Abbotsbury	Baseline	20	18	13
	Follow-up	20	18	15
Avalon	Baseline	20	18	18
	Follow-up	20	19	18
Tudor Bank	Baseline	46	37	16

	Follow-up	46	40	20
Greenacres	Baseline	41	39	13
	Follow-up	41	32	8
Meadowbank Ward	Baseline	13	12	12
	Follow-up	13	13	13
Cherry Ward	Baseline	11	11	11
	Follow-up	11	11	11
Hollins Park	Baseline	18	11	11
	Follow-up	18	14	13
Leigh Ward	Baseline	23	19	16
	Follow-up	23	19	11
Larkhill Hall	Baseline	66	60	44
	Follow-up	66	66	46
Cressington Court	Baseline	56	44	32
	Follow-up	56	40	31
Whiston& Halton Wards	Baseline	20	18	18
	Follow-up	20	18	13
Macclesfield	Baseline	15	11	11
	Follow-up	15	11	11
Finch Manor	Baseline	89	72	55
	Follow-up	89	71	55
Thomas Leigh	Baseline	20	18	18
	Follow-up	19	18	18
St Luke's	Baseline	56	54	54
	Follow-up	56	50	50
The Harbour	Baseline	36	28	28
	Follow-up	36	29	28

## ***Informed Consent***

Obtaining informed consent is always an ethical dilemma when working in dementia care, particularly when working at the later stages of dementia. By the fact that people are in care homes or on a dementia ward they are likely to be at later stages of dementia. The team acknowledged that people at later stages of dementia, and particularly those without carers, are vulnerable to potential abuses of the Rights and it was therefore important that they were included in study. Every attempt was made to obtain informed consent with every potential participant in line with the Mental Capacity Act <sup>[62]</sup>. Experienced clinical staff assessed the capacity of each potential participant, in line with best practice in research governance and the recommendations of the Mental Capacity Act, and individuals gave (or withheld) consent if they were able to consent themselves. If people were not able to give informed consent they were not asked to complete the self-report measures. Although the QOL-AD was chosen specifically because it is claimed to be suitable for people at later stages of dementia it was felt reasonable to assume that if people were unable to give informed consent completion of the measure would be too cognitively complex. There was no reason that people without a family caregiver be excluded from the study if they could give informed consent to participate.

Where possible, when a person was unable to give consent and therefore unable to complete the self-report measures someone (either a family carer or staff member) was invited to complete a proxy QOL-AD on their behalf.

If someone was unable to give informed consent, and therefore not included in the self-report element of the study they could still however be included within Dementia Care Mapping in cases where a Nominated Consultee could be identified and consulted. Where it was not possible to identify a Nominate Consultee, or if the Consultee advised against including the individual in the study, the person was not included in any aspect of the research. Informed consent was sought at both baseline and follow up. Figure 2 is a flow chart outlining these issues.

## **Ethical Arrangements**

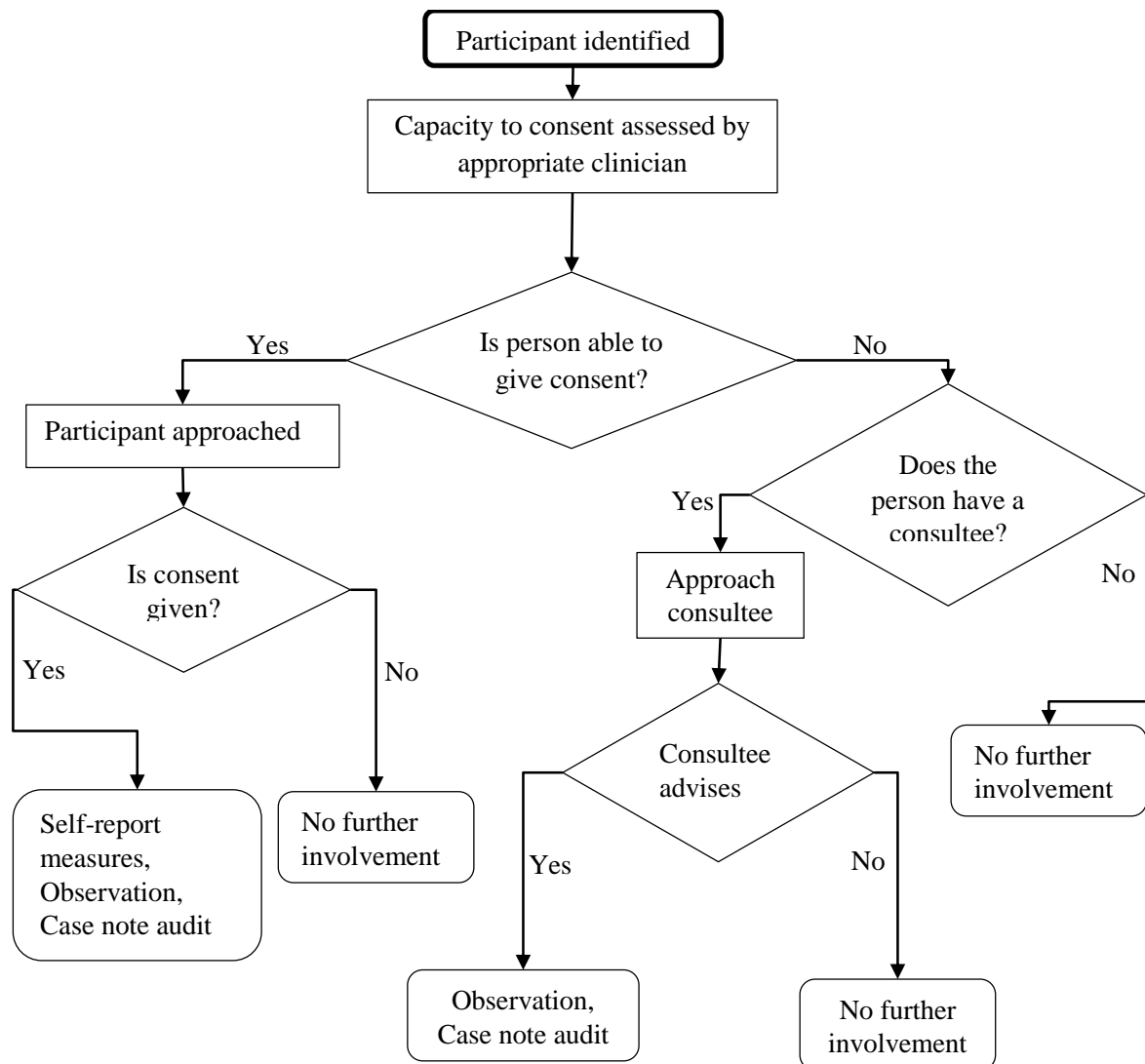
Both research assistants had regular contact with other members of the research team and were encouraged to share any concerns that they may have encountered during data

collection. In addition a Trial Steering Committee (TSC) and Data Monitoring and Ethics committee (DMEC) were established, and met regularly. Any serious concerns and issues which may have reached the threshold of a serious adverse event (SAE) were taken to the TSC and/or DMEC as appropriate and discussed thoroughly. Minutes of these meeting were kept and shared with NIHR. No reportable SAEs were identified during the study. Issues which were discussed with the committees as potential difficulties included changes to the protocol (which are outline later in this report) and concerns over quality of care.

## **Randomisation**

Randomisation of clusters was achieved by secure web access to the remote randomisation system at NWOOTH, Bangor University, using a dynamic adaptive randomisation algorithm<sup>[63]</sup>. The randomisation was performed by dynamic allocation to protect against subversion while ensuring that the trial maintained good balance to the allocation ratio of 1:1 across the trial. The complete list randomisation system was used therefore there was an exact allocation of the sites to groups. No stratification variables were used for randomisation. It is recognised that randomisation would usually take place after baseline measures had been completed in order to avoid any biases generated by the knowledge of which group you are in. In this study, however, this was not possible. Sites needed to know in advance when their training would take place in order to make the practical arrangements to attend the training e.g. ensuring adequate staff cover for the site. Similarly, if baseline measures were completed too far in advance of the training taking place there was a risk that factors other than the intervention may influence any change identified. For this reason sites were randomised prior to baseline measures being collected. In order to minimise the effects of allocation to group prior to baseline measures being taken the information given about the exact nature of the training provided, particularly its focus on Human rights, was only be revealed to those staff who need to know this in order to plan e.g. ward manager.

**Figure 2:** Flow diagram to illustrate process of consent and participation



### ***Allocation Concealment***

A web based system was used for randomisation, using cluster randomisation to randomise each recruited site. A complete list randomisation was used, therefore an even number of sites were entered into the system and allocated at random, half to care as usual group and half to the training group. The result of the randomisation was not seen until the randomisation has been completed. The result of the randomisation was only seen by people with access to the system. It was also possible to provide a blinded allocation report

for the people who need to be blinded to group allocations, groups were named Group 1 and Group 2 rather than Control and Intervention.

### ***Implementation***

The random allocation sequence was generated by the web-based system following recruitment. The sites were enrolled by the trial team, specifically the trial manager, Sarah Butchard. Assignment of sites to control or intervention was completed by the web-based randomisation system. If a service user was willing and able to consent to participate in the study, they were included. Consent was obtained directly from the service user if possible, if not then a proxy, usually a member of staff, was asked to provide a proxy on their behalf.

### ***Blinding***

Service users, research assistants who were collecting the data and the trial statistician were blinded. Service users would receive daily care and would not know whether staff had received the training or not. Staff members were obviously unblinded at follow up as they knew whether or not the unit had received the training. Research assistants were attending the site to complete assessments and did not know which group a site had been assigned to. The trial statistician was able to see the data labelled as group 1 and group 2. Unblinding of the trial results occurred at a results meeting attended by members of the independent monitoring committees.

## **Data Collection and Management**

Primary and secondary outcome measures were completed at baseline and then at 4 months after baseline. Figure 3 outlines the data collected at each time point. All measures were completed by two research assistants who spent a week at each unit completing measures at each time point.

Dementia Care Mapping was completed first at each site to reduce the chances of the research assistants becoming unblinded at follow up, as it was less likely that they would



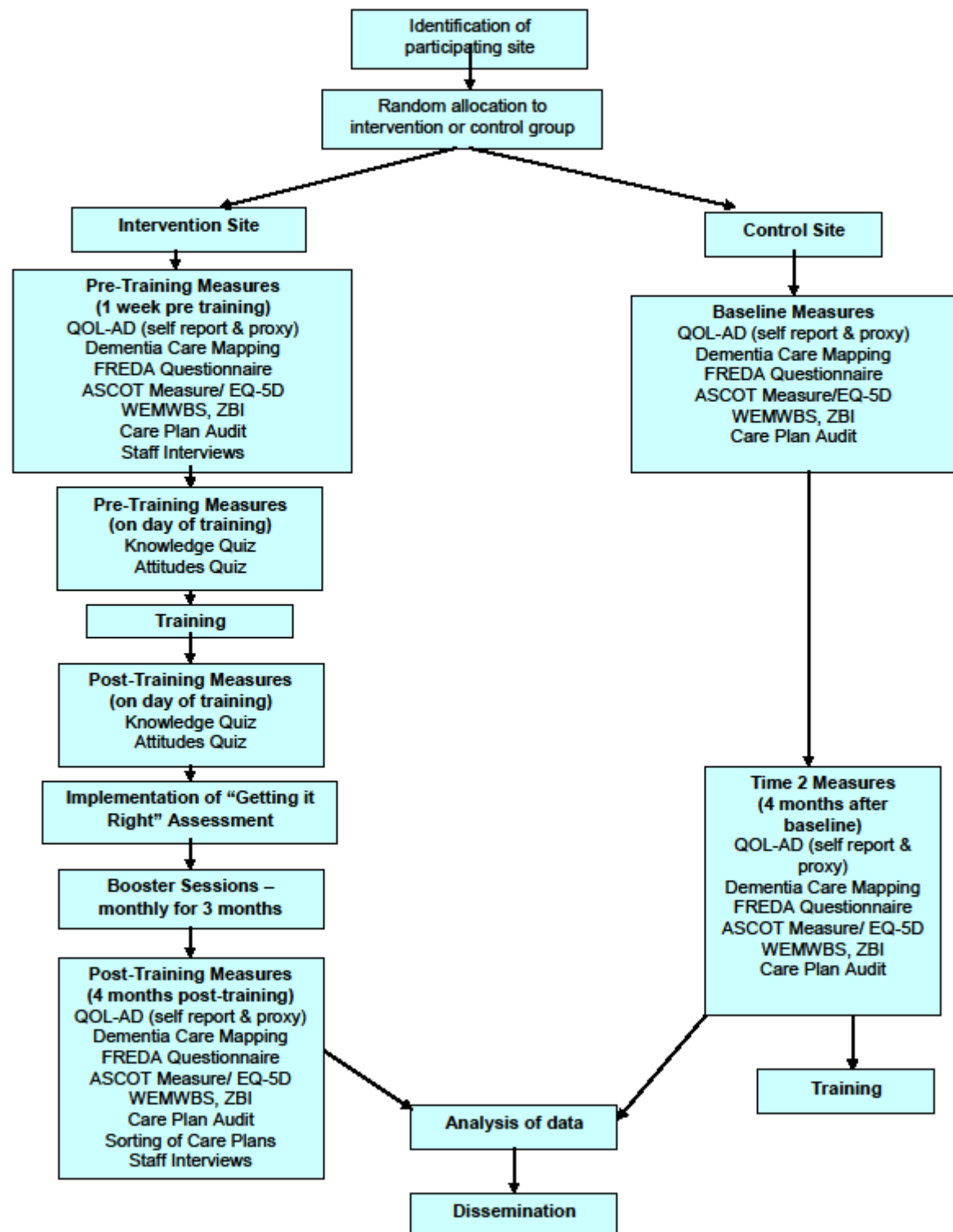
come across the assessment tools during this process. Table 5 shows the breakdown of tasks at each site.

**Table 5:** Breakdown of tasks at each site

Day	Planned Activities
1	Dementia Care Mapping
2	Care Plan Audits
3	Self-Report/Proxy Measures Staff Interviews
4	Self-Report/Proxy Measures Staff Interviews
5	Self-Report/Proxy Measures Staff Interviews

All research data was collected on paper at site and considered the source data. This data was then stored at the University of Liverpool for entry into the electronic system. This source data relevant to the participant's outcome measures was managed through MACRO an electronic data capture system provided by NWORDH. MACRO is an electronic data capture system which meets regulatory compliance for designing electronic case report forms (CRFs), data entry, data monitoring and data export, and good practice guidelines. MACRO has built in systems for an audit trail and quality assurance.

**Figure 3:** Flow chart to illustrate the process of data collection



A step by step cleaning process was implemented for the trial data and was outlined in the data management plan written for the study. A 5% random sample of the CRFs at each time point were selected for source data verification. This essentially involved cross checking the data held in MACRO with the paper source data. If the percentage error rate for each site was above 2% then further checking was initiated based on the finding. A further 10% of randomly chosen CRFs could be checked or if a systematic error be found with a particular item detailed checking of that item would be completed.

Further screening of the data was completed at all time points to identify outliers of potential errors.

### **Development of the Intervention**

The intervention for this trial was the introduction of a novel Human Rights based assessment tool, 'Getting it Right', into dementia wards and care homes. This tool was rooted in the principles of person centred care and was specifically developed by Mersey Care NHS Foundation Trust in order to improve the person centred nature of care plans and ensure that the Human Rights of the service user were considered. Following Human Rights training by the British Institute of Human Rights, the 'Getting it Right' Assessment<sup>[64]</sup> was developed by a Project Team at Mersey Care NHS Trust consisting of service user representatives, carers, researchers and staff from different disciplines including nursing, clinical psychology, occupational therapy and psychiatry.

The tool was designed to be completed by a staff member and the service user collaboratively, and thus, encouraged both parties to consider the different Human Rights that should be recognised during the service users stay in care. More specifically, the tool maps these Human Rights on to a wide range of areas of care including, preferences of food and drink, preferred name and access of visitors. The function of the tool was to generate a person centred care plan that would maximise the person's quality of life whilst they were on the unit and help to ensure that their Human Rights are acknowledged and upheld. The staff member was supported by a corresponding manual and the end product was a care

plan which could be kept by the service user as well as serving as the basis for the subsequent care the person will receive. The tool was designed to be user friendly with bold print, pictorial representations and clear colour coded sections.

To aid the implementation of the Assessment Tool a Training Package was also developed for staff. This took the form of one day training, split between providing a general introduction to Human Rights and their relation to health care and providing advice and instructions on how to correctly administer the assessment tool. The training package utilised 'dilemma-based learning' <sup>[34]</sup> and included a specially designed and commissioned DVD, containing dramatised care-based scenarios, which encourage interactive learning of Human Rights based approaches when making clinical decisions. During the training, participants were encouraged to engage in discussion around how to respond to clinical situations from a Human Rights focused approach. As such it was framed as adopted the Values and Awareness model of Human Rights training <sup>[35]</sup>.

The training was designed to be delivered to all grades and professions of staff on a care unit. This was the model used in the pilot phase where staff attending training encompassed a range of grades and professions e.g. ward manager, registered nurses, support workers, domestic staff, occupational therapists, physiotherapists. The key issue was that training is provided for the team as a whole in line with evidence that this increases discussion of the issues and allows staff to support each other in embedding the training into practice.

Following the initial training, each site was also offered 3 monthly booster sessions to help build their confidence in embedding a Human Rights Based Approach to care.

The Getting it Right tool and associated Training Package were piloted within Mersey Care NHS Foundation Trust, and underwent an evaluation using a number of the outcome measures; a specifically designed audit tool, vignette based semi-structured interviews and Human Rights knowledge and attitude quizzes.

## Outcome Measures

### Primary Outcome Measure

**Service user well-being:** The primary outcome measure used in the research was the Quality of Life in Alzheimer's disease <sup>[53]</sup> to assess the subjective well-being of the person with dementia. The European consensus on outcome measures for psychosocial intervention research in dementia care <sup>[65]</sup> states that the QOL-AD is the measure of choice when looking at Quality of Life as it is brief, has demonstrated sensitivity to psychosocial intervention, correlates with health-utility measures, and can be used by people with MMSE scores as low as 3.

The QOL-AD proxy version was also used with both staff and family caregivers to elicit the views of a person supporting the individual with dementia.

### Secondary Outcome Measures

**Family Carer well-being:** It is recognised that caring for someone with dementia can be a stressful role <sup>[66]</sup>. Carer well-being was therefore also assessed to explore whether the application of a Human Rights Based Approach on a unit improves the well-being of the family carer. Family carer well-being was assessed via the Warwick Edinburgh Mental Well-Being Scale (WEMWBS) and the Zarit Burden Interview (ZBI) explored their perception of caring responsibilities.

**Standard of Care:** A care plan audit was conducted at each site to provide a measure of the documented plan of care for each service user. An audit tool was specifically designed for the study, based on the gold standards of person centred care in dementia care settings as outlined in the Enriched Care Planning for people with dementia model <sup>[50]</sup> and with a Human Rights Based focus. The aim was to establish whether Human Rights Based training is an explanatory variable in any changes in care and well-being observed over and above a standard training package as it allowed for presence of Human Rights based language and concepts in care plans to be directly assessed.

The standard of care provided at the site and its link to well-being was assessed via Dementia Care Mapping <sup>[67]</sup> - an observational assessment yielding quantitative measures of well-being and ill-being for the individual with dementia.

**Staff decision making:** Decision making was explored via vignette based interviews with staff at various grades at the participating sites. It was felt that this qualitative element of the study served several purposes. It provided an outcome in its own right in that it explored how staff makes decisions in difficult complex situations. The interviews also aimed to provide more information on the mediators of any effect observed as it asks directly about decision making and what assists with this. If the intervention was successful more human rights based language and a clearer framework for decision making should be seen in the post intervention interviews.

**Knowledge of Human Rights:** In order to assess knowledge acquisition during the training pre and post-training measures of Human Rights knowledge were collected via the Human Rights Knowledge Quiz, as recommended by “A Guide to Evaluating Human Rights Based Interventions in Health and Social Care” <sup>[37]</sup>. This data was collected on the day of the training. A Human Rights Attitude Quiz was also be used to look at changes in attitude pre and post training. Again this data was collected on the day of training.

**Health Economics:** The trial also conducted a cost consequence analysis where consequences include: patient reported health related quality of life (EQ-5D), patient reported well-being (QoLAD), family member well-being (WEMWBS and ZBI) and overall quality of care (ASCOT).

### **Development of Outcome Measures specific to the study**

**Care plan audit tool** - A care plan audit tool was developed specifically for the study as there was no existing measure available which would capture the information required, that is the person centred nature of the care plan and specific references to Human Rights language. The audit tool was based on the gold standards of person centred dementia care as laid out in the Enhanced Care Planning for dementia document derived from Kitwood’s principles of person centred care.

The audit tool employed a 'tick box' format and data could therefore be expressed as a percentage as well as a raw number for baseline and follow up data and then compared formally. There is however also the capability to capture more qualitative data which would allow for reflection on the person centred nature of care plans and the inclusion of Human Rights Based language in care plans. If the intervention was successful it would be anticipated that care plans post training would be more person centred and include more Human Rights Based language.

***Vignette based interviews*** - Interview schedules were developed by combining the areas of enhanced care planning from Kitwood's model of dementia care and the Human Rights considered most relevant to health care. Ten vignettes were constructed which, between them, covered all relevant areas using examples from clinical practice. Using hypothetical examples such as these avoided asking directly about care provision which may not lead to responses that reflect true practise due to demand characteristics and staff concerns about the perceived potential repercussions of their responses.

***Knowledge and Attitudes questionnaire*** - The Human Rights Knowledge and Attitudes Quizzes were adapted from the original learning disabilities questionnaires outlined in "A Guide to Evaluating Human Rights Based Interventions in Health and Social Care" <sup>[37]</sup>.

### **Issues of Specificity**

It is important that the outcome measures utilised allowed exploration of the specificity of the intervention in improving care and well-being over and above the application of general training. This has been addressed in a number of ways:

- The care plan audit measured the documented standard of care that a person should be receiving but will also tapped into increases in Human Rights based language and concepts which would be suggestive of the Human Rights Based nature of the intervention having an effect over and above simply providing generic training.

- The completion of Human Rights knowledge and attitude quizzes measured changes in these areas pre and post training but does not look at the impact this has on staff in their everyday working lives and how it affects service user well-being.
- Staff interviews were conducted to explore whether the introduction of a Human Rights Based Approach leads to differences in their decision making processes when considering care issues. Again this will be evaluated through the identification of key phrases and concepts in the transcripts which would point to the specificity of a Human Rights Based Approach having a direct influence on daily decision making.
- The FREDa based questionnaire enabled the team to explore whether service users feel that their Human Rights are respected and upheld more after the intervention.

Taken together these elements allowed evaluation of the proposal that the Human Rights Based Approach outlined in this proposal had benefits that would not be seen by generic training.

### **Development of the FREDa Assessment tool**

Although there is recognition that violations of human rights can occur in healthcare settings little has been done to attempt to quantify the extent to which this occurs. To this end, work was undertaken to develop and begin validating a questionnaire measure based on the FREDa principles in order to assess how well individuals subjectively experience their Human Rights as being upheld.

The FREDa (Fairness, Respect, Equality, Dignity and Autonomy) principles have been used elsewhere within healthcare to aid individuals' understanding of their Human Rights <sup>[68]</sup>. However the validity of these constructs has not been empirically tested. Therefore the initial stage of this tool development was to consult with service users and their carers.

Items for the FREDa questionnaire were first generated via focus groups with people living with dementia and their carers. Participants came to one of two focus groups to discuss the care they had received in relation to their Human Rights. The main aims of the focus groups



were to investigate whether the FREDA principles adequately covered areas relevant to dementia care, along with eliciting examples of when such principles were valued or disregarded. All participants consented to the data generated by the focus groups being used in relation to the development of the Human Rights agenda.

People at later stages of dementia are often excluded from consultation due to the increased communication and comprehension difficulties that can arise as the condition progresses. Given that this measure would be exploring the potential violations of an individual's Rights it felt important that this group of people who may be vulnerable in relation to having their Human Rights undermined were included in consultation. A method developed by Kate Allen <sup>[69]</sup> was utilised which involves showing the person living with dementia a picture of an unknown person and asking them to reflect on how that person would feel in a particular situation and what advice they would give them. It is suggested that this elicits more information than asking direct questions about the treatment that they have received. This method was used on a dementia inpatient ward within Mersey Care NHS Foundation Trust and the information elicited was incorporated into the data collected from the focus groups.

Following the focus groups and ward interviews the information was themed and statements developed that reflected these themes. Grouping these statements together revealed 4 overarching themes; identity, dignity, empowerment and autonomy. The developing questionnaire was therefore named the IDEA questionnaire.

The resulting questionnaire was piloted with a group of people living with dementia in the community. From this piloting phase some changes were made related to the structure and phrasing of items on the measure e.g. removing any double negatives from the questions.

## **Changes to Protocol**

Despite it being suggested that the QOL-AD is suitable for people whose MMSE scores would imply severe symptoms of dementia, in practice it became evident very quickly that there

were limited numbers of people living with dementia on the inpatient wards and care homes who were able to complete the self-report version of the measure. Whilst every effort was made to identify and recruit all service users at a site that could complete the self-report version it was also necessary to utilise proxy reports for those people who could not complete the questionnaire themselves. In these cases a family caregiver was first sought and if none was identified a member of staff was requested to complete the proxy version. In total 357 proxy measures were completed and of these 345 were completed by staff members.

Although the initial aim was to recruit 50% of staff from each site to interview it soon became apparent that this would not be practical. At each site there were a percentage of staff who worked only nights and there were also many staff who were not available on the data collection week due to annual leave, rota patterns etc. Therefore a more pragmatic approach was taken and 8 staff members per site were recruited to complete the decision making interviews.

While it was initially envisaged that booster sessions would last 2 hours this was not practical when visiting the sites. In general managers were not happy to release staff for this length of additional time and chose to speak directly to the team members themselves rather than involving other members of the staff. Many of the booster sessions were refused.

It was proposed that the Alzheimer's disease Assessment Scale – cognitive subscale (ADAS-Cog) be used to compare the cognitive abilities of people living in care homes and people on NHS wards. In practice the majority of people living with dementia were unable to complete the assessment and a large number of people also refused to complete it. Given the small numbers collected it was not possible to make a comparison between the two groups. For this reason no attempts were made to complete the scale at follow up.

A smaller number of carers than expected were recruited to the study. The research assistants were surprised by the lack of visitors many residents in care homes had and many times when carers did visit they did not want to complete questionnaires as they felt that

was their time to visit the resident. As a result the numbers of questionnaires completed were not large enough to make meaningful comparisons.

## **Statistical Analysis**

### **Missing data**

There are two types of missing data possible within this dataset. Missing items within questionnaires at a time point and missing measures at a time point.

For items missing within a questionnaire the following approach was taken. If a missing value rule exists for a questionnaire then this was utilised. Over and above this is 25% or less of the items in a questionnaire were missing then these were replaced with a pro-rated individual's item score.

It was expected that there would be participants missing at follow up who were present at baseline and vice versa and so the analysis model was influenced by this. The data was assessed for differences between those present at both baseline and follow up to those present only at baseline for possible predictors to be included in the sensitivity models.

### **Baseline characteristics**

Participant demographics including age and gender were reported split by allocated group, for baseline and follow-up. The type of dementia patients were living with was also included where appropriate. There was no statistical comparison of the data for the two groups.

### **Interim analyses**

No interim analyses were planned or scheduled to be completed. During the course of the trial, no additional analyses were identified or requested by the DMEC.

### **Primary effectiveness analyses**

The original model of analysis was planned to be a multi-level analysis of covariance (ANCOVA) model. Due to the nature of the wards and care homes it was reasonable for the

participants present at baseline not to be present at follow up for a number of reasons. Therefore, a linear mixed model was used to assess the effect of time (baseline or follow-up) and group (control or intervention) and interaction of time and allocated group. The model also included site as a random effect. The main effect of interest was the group effect.

As it became evident that the ability to collect self-report data on the primary outcome measure was limited proxy data was collected in the absence of self-report data. An additional term (self-report vs. proxy) was added to the model to assess the importance of this difference. If it was found that this term is significant then separate analyses of self-report and proxy data would be completed. This understandably affects the amount of data available for the analysis and would have implications for the power of the study. The alternative was to include a self-report vs proxy and condition (group) interaction. This assesses whether there is a consistent difference between self-report and proxy data in both groups. The former model of analysis was chosen to allow simpler more intuitive understanding of the data. Either way the power of the models that could be applied would have been affected by the implications of using a mixture of proxy and self-report data.

### **Secondary effectiveness analyses**

A linear mixed model was applied for all secondary outcome measures where appropriate. For the Knowledge and attitudes questionnaire data was collected pre and post training for the intervention group and only at baseline for the control group. This precluded the use of the linear mixed model to establish a group effect, therefore a paired samples t-test was used to establish whether there was a difference in score before and after training was presented.

### **Additional analyses**

As indicated the significance of covariates, namely, age, gender, dementia care mapping score, dementia type and whether the person had a carer or not were investigated by adding these to the linear mixed model.

It was also noted that one site had a different follow up time to the other sites with only 11 weeks in follow up rather than the established 16 weeks. This nuance was investigated by allowing the time variable to vary for this site.

## **Economic analyses**

Based on the Medical Research Council (MRC) guidelines for the evaluation of complex interventions <sup>[70]</sup> and our Standard Operating Procedure for economic evaluation alongside pragmatic RCTs, and experience in the conduct of economic evaluation alongside trials of psychosocial interventions in dementia care <sup>[71, 60]</sup> we, from a public sector, multi-agency perspective <sup>[72-77]</sup>:

1. Fully costed the human rights staff training programme, distinguishing between set up/training costs and running costs, with the former amortized over 3 years.
2. Produced descriptive statistics for study participant medication use, primary and secondary care health service use and social care, focusing on admissions to hospital for participants in care homes (using where possible, routine hospital and care home data). Service usage was costed using National unit costs <sup>[68, 78]</sup>.
3. Conducted a cost consequence analysis where consequences included: patient reported well-being (QOL-AD), family member well-being (WEMWBS and ZBI) and overall quality of care (ASCOT).

The EQ-5D 3L was included for participants with mild to moderate dementia, to allow comparison with other published studies, and previous trials, but a cost consequence approach rather than cost-utility analysis was undertaken because of the range of relevant outcomes spanning the person with dementia, their family members, hospital and care home staff and objective measures of care quality.

## **Dementia Care Mapping (DCM)**

Dementia Care Mapping (DCM) is an observational tool. A trained observer (mapper) records the behaviours of several participants for a certain amount of time in order to gain an insight into participant's day-to-day experience. Due to ethical reasons, observations can only take place in communal areas. After a 5 minute period, the mapper records a Behaviour Category

Code (BCC) indicating what the individual was doing. Alongside this, a Mood and Engagement Value (ME) is also recorded indicating how engaged the individual was and if their mood was positive or negative. Table 6 summarises the definitions of each score for mood and engagement.

DCM is an established approach that looks at person centred care in practice. This measure was completed for all sites at both baseline and follow up. The study focused on one aspect of DCM that records the mood and engagement levels of up to 8 participants living with dementia within a 6 hour time frame. The ME Score for each unit at both baseline and follow up were recorded and compared to look for changes in quality of care provided.

**Table 6:** Summary of mood and engagement values <sup>[79]</sup>

Mood	ME Value	Engagement
<b>Very happy, cheerful. Very high positive mood.</b>	+5	Very absorbed, deeply engrossed/engaged.
<b>Content, happy, relaxed. Considerable positive mood.</b>	+3	Concentrating but distractible. Considerable engagement.
<b>Neutral. Absence of overt signs of positive or negative mood.</b>	+1	Alert and focussed on surroundings. Brief or intermittent engagement.
<b>Small signs of negative mood.</b>	-1	Withdrawn and out of contact.
<b>Considerable signs of negative mood.</b>	-3	
<b>Very distressed. Very great signs of negative mood.</b>	-5	

## Qualitative Analysis

There were two sets of data within the study which were analysed qualitatively. These were the staff decision making interviews and the post study interviews with intervention sites. Both sets of data were analysed using thematic analysis as outlined by Braun and Clarke <sup>[80]</sup>. Thematic analysis is a method for identifying, analysing and reporting patterns (themes) within data. At its most basic it organises and describes the data set in rich detail. In reality however it frequently goes further than this, and interprets various aspects of the research topic <sup>[81]</sup>. Table 7 outlines the stages of thematic analysis proposed by Braun and Clarke.

Table 7: Phases of thematic analysis

Phase	Description of the process
1. Familiarising yourself with your data	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas.
2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code.
3. Searching for themes	Collating codes into potential themes, gathering all data relevant to each potential theme.
4. Reviewing themes	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis.
5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme.
6. Producing the report	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis.

## **Staff Interviews**

Data from the staff decision making interviews was initially analysed as one data set using thematic analysis, as outlined by Braun and Clarke <sup>[80]</sup>. An inductive or 'bottom up' approach <sup>[82]</sup> to data analysis was taken. An inductive approach assumes that the themes are derived directly from the data <sup>[83]</sup> as opposed to imposing the data onto a pre-existing model.

From this analysis themes were identified related to staff decision making strategies. Themes were not combined as fully as they would usually be in thematic analysis as it felt important to identify specific, rather than general, decision making strategies in this context. The interviews were then reanalysed to identify the frequency with which these strategies were discussed in each group i.e. Intervention baseline, Intervention follow up, Control baseline and Control follow up.

## ***Post Training Interviews***

Semi-structured interviews were conducted with staff at intervention sites on an opportunistic basis. This included managerial staff, members of staff who attended training and those that did not attend training. The interviews were completed by a research assistant and a member of the PPI reference group. Interviews were recorded, transcribed and inductively then subsequently deductively analysed using thematic analysis. Each site was individually analysed to identify the main themes from each site. The main theme of management style was then deductively analysed using characteristics from Bass and Alvolio <sup>[84]</sup> characteristics of active/ transformational and passive/ transactional management style to identify descriptions of these characteristic within each site and how these impact on descriptions of the relationships between service user and family members with staff. Some sites were unable to accommodate the interviews due to changes in management and lack of staffing.



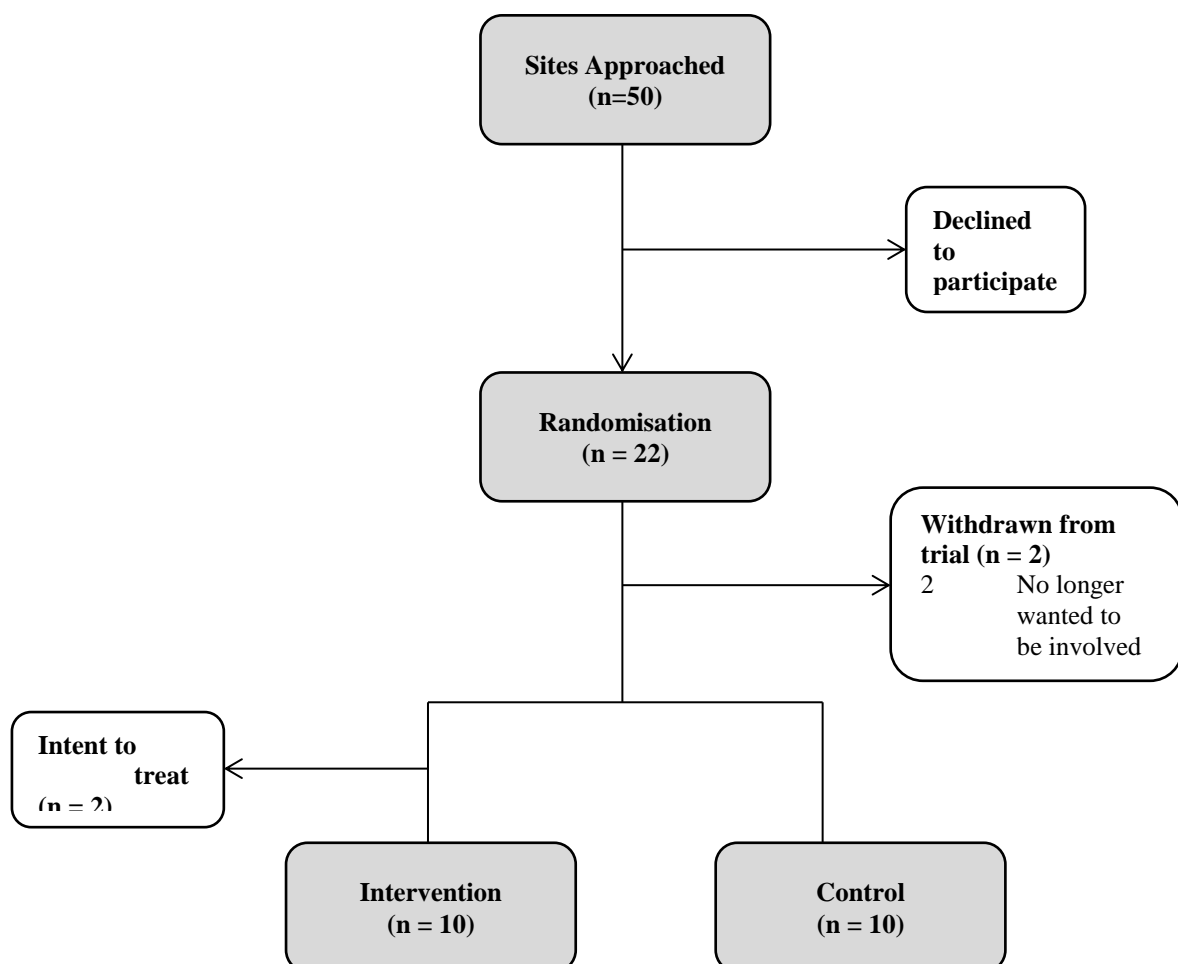
## Chapter 3 - Trial Results

### Flow of participants in the trial

#### Sites

In total, 50 sites were contacted and offered the opportunity to be involved in the study (care homes n=34, NHS wards n=16). Twenty eight sites declined to participate therefore 22 were randomised as either intervention or control. In between randomisation and data collection two sites opted out of the study as they no longer wanted to be involved. These sites had previously been randomised and withdrew due to change of management. Of these sites one had been randomised as a control site and one as an intervention site. During data collection 2 intervention sites did not complete training, therefore were classed as intent to treat (their data was still included in the intervention group's analysis). The reason given for not completing the training at both sites was lack of time and resources to release staff to attend the training. One of these sites accepted a 'booster' session and wished to use the 'Getting it Right' assessment tool. The recruitment of sites to the study is outlined in figure 4.

**Figure 4:** Number of sites approached and recruited to the study



## Overall Recruitment

In total the study recruited 439 people living with dementia with 213 in the intervention arm of the study and 226 in the control arm. These people may have completed self-report measures, had proxy measures completed about them, been observed in dementia care mapping or being involved in the care plan audit. They may have completed one, or more than one element of the study. Table 8 summarises the number of aspects of the study that participants were involved in.

New participants could be recruited at follow up. Sites rather than participants were randomised to receive control or intervention, and participants did not receive control or intervention. This was an expected feature of recruitment, since it was expected that participants may not still be at the same site from baseline to follow-up. Recruitment from each site, for baseline and follow-up, was based on the individuals present at the site at the time of the baseline or follow-up visits.

**Table 8:** Number of aspects service users recruited to the study were involved in (self-report/proxy measures, DCM and care plan audits).

Baseline			Follow-up		
1	2	3	1	2	3
93	124	115	80	122	120

Additionally 245 staff members were recruited to the study.

## Staff Completing the Training

The aim was to recruit as many staff as possible from each intervention site to the training day. In practice this was extremely difficult and even when multiple training days were offered site managers reported it being extremely difficult to release staff. Table 9 summarises the number of staff trained at each intervention site and the number of booster

sessions that each site accepted during the duration of the intervention (i.e. the 3 months following the training).

**Table 9:** Staff attending the training day and number of booster sessions accepted at each site

Site	Day staff at site	Staff Trained	Percentage of staff trained	Booster sessions
Dale Park	38	8	21.1%	3
Finch Manor	51	22	43.1%	2
Meadowbank	23	6	26.1%	2
Greenacres	20	6	30.0%	2
Cherry Ward	23	6	26.1%	3
Hollins Park	21	11	52.4%	2
Larkhill Hall	37	7	18.9%	2
Macclesfield	43	5	11.6%	1
Abbotsbury	19	0	0%	1
St Luke's	51	0	0%	0

If the 2 sites who did not engage with the training are excluded an average of 8.88 staff per unit were trained which equates to 28.7% of staff being trained. There was a large range in the percentage of staff trained at a particular site (11.6% - 52.4%).

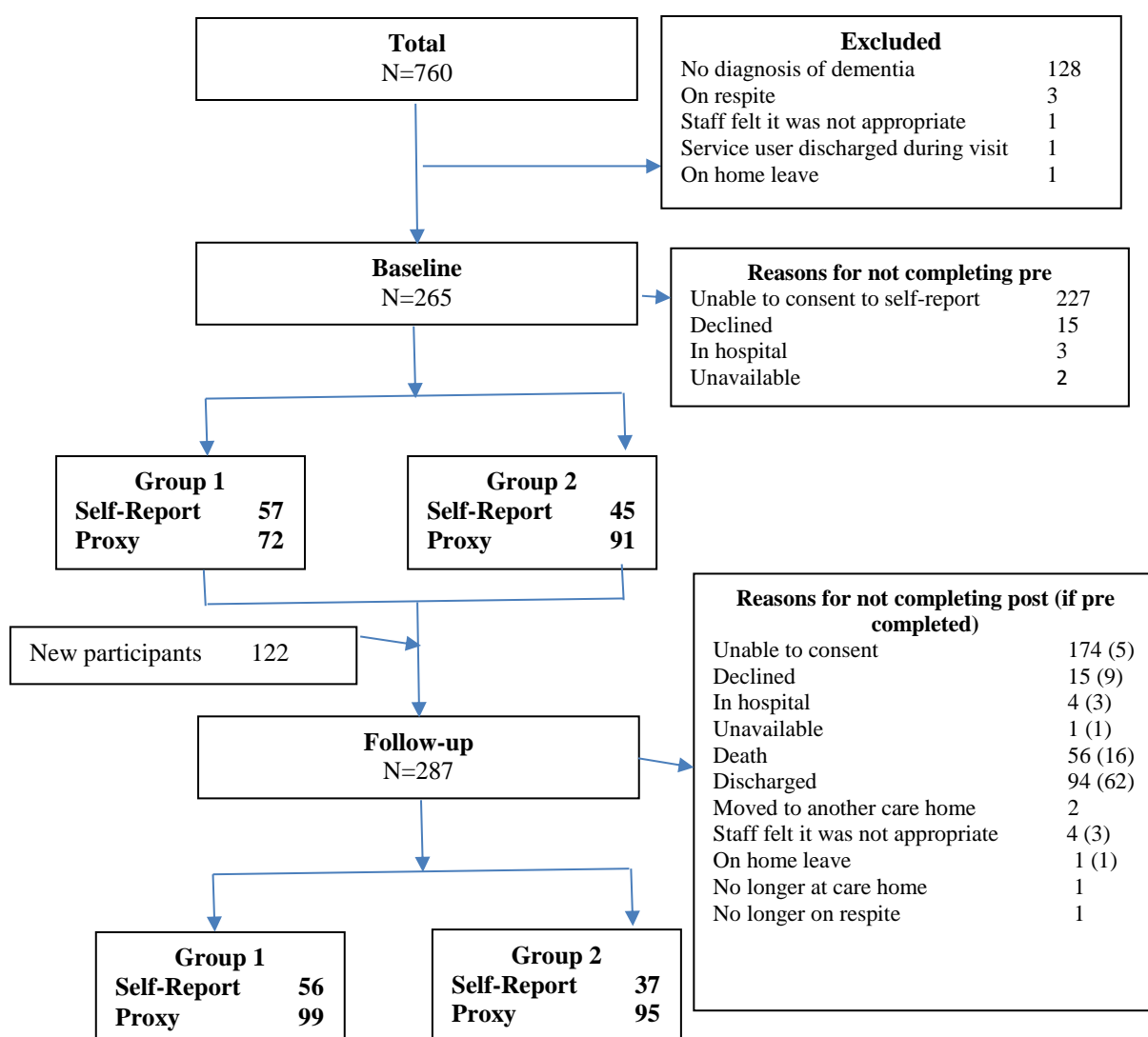
It was initially envisioned that the booster sessions would be sessions each month lasting 1-2 hours in which staff who had either attended the training, or who had not been able to attend the training but were completing the assessment tool could share their experiences and any difficulties or concerns could be addressed. This would be similar to a consultation style session and was aimed to be supportive in nature. In reality only 2 sites accepted all 3 booster sessions offered. Booster sessions were most often rejected due to lack of time. They were also often not utilised in the way that was initially expected. In the majority of the sessions the team member met with the manager of the unit alone who reflected on the

assessment tools. This did not meet the aims of allowing the staff to explore difficulties that were arising and to cement the learning obtained in the training session.

### Service Users Completing the Primary Outcome measure

One hundred and forty nine service users were able to self-complete the primary outcome (QOL-AD) and a further 256 proxies were recruited to complete the QOL-AD. Figure 5 outlines the flow of participants completing the QOL-AD at each time point.

**Figure 5:** Time points and number of service users/proxy's completing the QOL-AD.



The most common reasons for not completing the follow up visit after completing the baseline visit were death and being discharged from the care home or hospital ward. Differences in demographics and outcome results were tested for; in the groups who died and those who did not die, and the groups who were discharged and who were not discharged.

The age of the participants who died (87.0 (7.4)) was significantly higher than the age of participants who did not die (81.4 (7.6)),  $t(320) = -2.867$ ,  $p=0.004$ . The QOL-AD score of participants who died (28.93 (5.35)) was significantly lower than the QOL-AD score of the participants who did not die (32.85 (7.21)),  $t(242)=2.002$ ,  $p=0.046$ .

The age of the participants who were discharged (78.4 (7.7)) was significantly lower than those who were not discharged (82.5 (7.4)),  $t(320) = 3.840$ ,  $p<0.001$ . There was a significant difference in the proportion of males and females in the not discharged and discharged groups  $\chi^2(1)=9.219$ ,  $p=0.002$ . The reason for this is that the group who were not discharged have a higher proportion of females (63.0%) than males (37.0%), whereas the discharged group have a higher proportion of males (58.1%) than females (41.9%).

### **Staff Interviews**

A total of 245 staff members were interviewed during the course of the study. 101 members of staff completed an interview at baseline only, 88 members of staff completed an interview at follow up only and 56 members of staff completed interviews at both time points. This yielded a total of 301 interviews. Table 10 summarises the number of interviews completed by staff at both baseline and follow up in the control and intervention groups.

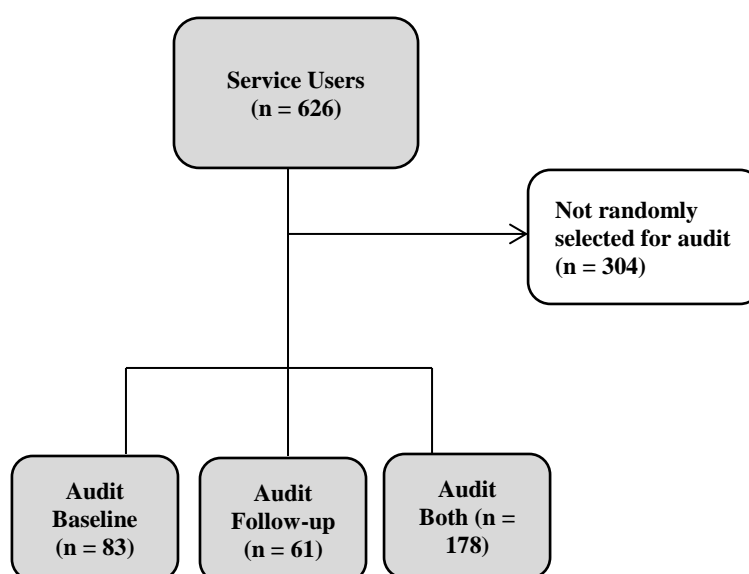
**Table 10:** Number of interviews completed at each time point in control and intervention sites.

	Baseline	Follow up	Total
Control	77	70	147
Intervention	79	75	154
Total	156	145	301

### Care Plan Audits

At each site 50% of eligible service users were randomly selected to participate in the care plan audit aspect of the study. Figure 6 outlines the number of service users involved in the care plan audits at each time point whilst table 11 summarises the reasons that care plans were not selected for audit.

**Figure 6:** Time points and number of service users involved in care plan audits.



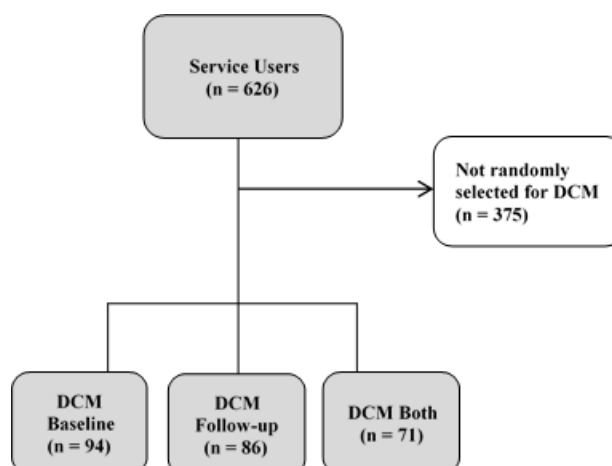
**Table 11:** Reasons for care plans not audited.

Reasons at Baseline	Total
Not randomised for selection	242
New service user at follow-up	125
Declined	1
In hospital	1
Not available	1
Reasons at Post	Total
Not randomised for selection	236
Declined	12
In hospital	3
Not available	1
Service user passed away	48
Service user discharged	93
Not appropriate	4

### Dementia Care Mapping

At each site 8 service users were randomly selected to participate in DCM. Figure 7 shows the number of potential participants and those involved at each time point.

**Figure 7:** Time points and number of service users completing DCM.



## Maintenance of 'blind' assessments

While it was the intention for the attending researchers not to be aware of the sites allocation while they were completing the assessments in some cases this was unavoidable. Unblinding occurred 3 times at baseline and 4 times at follow up, so in total 7 sites were not blinded to the researchers by completion of the assessments. Table 12 summarises the reasons why researchers became unblinded to group allocation and when this unblinding process took place.

**Table 12:** Reasons as to why researchers became unblinded

Reasons at Baseline	Total	Time point at Baseline	Intervention / Control
Manager spoke about training	1	Day 5	Intervention
Human Rights training scheduled on staff rota	1	Day 5	Intervention
Informed by research team	1	Before collecting any data	Control
Reasons at Follow-up	Total	Time Point at Follow up	Intervention / Control
Manager asked when they would receive training	1	Before collecting any data	Control
Getting It Right toolkit present in care plans.	2	Day 1	Both Intervention
Informed by staff during interviews	1	Day 5	Intervention



## Characteristics of the samples at each time point

Tables 13 and 14 give the baseline and follow up characteristics (age, gender and type of dementia) respectively for each of the allocated groups.

**Table 13:** Baseline characteristics

	<b>Control</b>	<b>Intervention</b>	<b>Total</b>
	<b>Mean (SD) / N (%)</b>	<b>Mean (SD) / N (%)</b>	<b>Mean (SD) / N (%)</b>
<b>Age</b>			
Mean (SD)	81.2 (8.0)	82.2 (7.3)	81.7 (7.7)
<b>Gender</b>			
Female	93 (57.1%)	103 (60.9%)	196 (59.0%)
Male	70 (42.9%)	66 (39.1%)	136 (41.0%)
<b>Type of Dementia</b>			
Alzheimer's	55 (33.7%)	67 (39.6%)	122 (36.7%)
Vascular	46 (28.2%)	45 (26.6%)	91 (27.4%)
Dementia with Lewy Bodies	7 (4.3%)	2 (1.2%)	9 (2.7%)
Mixed	19 (11.7%)	14 (8.3%)	33 (9.9%)
Fronto-Temporal Dementia	2 (1.2%)	0 (0.0%)	2 (0.6%)
Other	29 (17.8%)	41 (24.3%)	70 (21.1%)
<b>Missing</b>	5 (3.1%)	0 (0.0%)	5 (1.5%)

**Table 14:** Follow up characteristics

	<b>Control</b>	<b>Intervention</b>	<b>Total</b>
	<b>Mean (SD) / N (%)</b>	<b>Mean (SD) / N (%)</b>	<b>Mean (SD) / N (%)</b>
<b>Age</b>			
Mean (SD)	81.1 (8.0)	82.0 (7.6)	81.5 (7.8)
<b>Gender</b>			
Female	120 (53.8%)	127 (59.6%)	247 (56.7%)
Male	103 (46.2%)	86 (40.4%)	189 (43.3%)
<b>Type of Dementia</b>			
Alzheimer's	77 (34.5%)	85 (39.9%)	162 (37.2%)
Vascular	61 (27.4%)	50 (23.5%)	111 (25.5%)
Dementia with Lewy Bodies	8 (3.6%)	4 (1.9%)	12 (2.8%)
Mixed	30 (13.5%)	15 (7.0%)	45 (10.3%)
Fronto-Temporal Dementia	3 (1.3%)	0 (0.0%)	3 (0.7%)
Other	38 (17.0%)	59 (27.7%)	97 (22.6%)
<b>Missing</b>	6 (2.7%)	0 (0.0%)	6 (1.4%)

Combining the diagnostic categories of 'Alzheimer's' and 'other' would yield figures (baseline – 57.8%, follow up – 59.8%) that are more in keeping with national prevalence figures for Alzheimer's which suggest 62% of people living with dementia are living with Alzheimer's type dementia<sup>[1]</sup>.

Table 15 gives the characteristics of staff recruited to the study in both the control and intervention group. The groups appeared to be similar in their characteristics and key features are that the majority of the staff members involved were white British females. There were far more unqualified than qualified staff recruited to the study.

**Table 15:** Staff demographics recruited for the study

	<b>Control</b>	<b>Intervention</b>	<b>Total</b>
	<b>Mean (SD) / N (%)</b>	<b>Mean (SD) / N (%)</b>	<b>Mean (SD) / N (%)</b>
<b>Age</b>			
Mean (SD)	39.3 (12.3)	39.5 (12.0)	39.1 (12.6)
<b>Gender</b>			
<b>Female</b>	94 (76.4%)	100 (80.6%)	194 (78.5%)
<b>Male</b>	29 (23.6%)	24 (19.4%)	53 (21.5%)
<b>Ethnicity</b>			
White/White British	104 (83.9%)	113 (91.1%)	217 (87.5%)
Black/Black British	5 (4.0%)	0 (0.0%)	5 (2.0%)
Asian/Asian British	6 (4.8%)	1 (0.8%)	7 (2.8%)
Mixed	3 (2.4%)	1 (0.8%)	4 (1.6%)
Other	4 (3.2%)	4 (3.2%)	8 (3.2%)
<b>Missing</b>	2 (1.6%)	5 (4.0%)	7 (2.8%)
<b>Qualified member of staff?</b>			
Yes	21 (16.9%)	19 (15.3%)	40 (16.1%)
No	102 (82.3%)	103 (83.1%)	205 (82.7%)
<b>Missing</b>	3 (0.8%)	2 (1.6%)	3 (1.2%)

See appendix 3 for a full list of job roles of the staff interviewed for the study.

## Primary analysis of outcomes

The primary ITT analysis did not demonstrate any evidence of a difference between the two treatment groups. The primary model fitted was as described with the model fitted using self-report/proxy, time point, allocated group and the interaction of time and allocated group as fixed effects and site as a random effect. Table 16 shows the mean values for the

control and intervention group scores on the QOL-AD (both self-report and proxy) at both baseline and follow up.

**Table 16:** Unadjusted mean values for the two treatment groups at the two assessment points for QOL-AD

Quality of Life in Alzheimer's Disease (QoLAD)						
		N	Minimum	Maximum	Mean	Std. Deviation
<b>Control</b>	Baseline	117	14.08	51.00	32.12	6.96
	Follow up	146	13.00	46.09	31.98	6.69
	Baseline SR	58	26.00	51.00	35.79	5.70
	Follow up SR	55	22.75	44.91	35.14	5.67
	Baseline Proxy	59	14.08	41.17	28.51	6.19
	Follow-up Proxy	91	13.00	46.09	30.07	6.56
<b>Intervention</b>	Baseline	127	15.00	48.75	33.09	7.34
	Follow up	127	16.55	45.00	32.99	6.38
	Baseline SR	45	26.00	48.75	37.56	5.03
	Follow up SR	38	23.83	45.00	35.61	5.49
	Baseline Proxy	82	15.00	47.67	30.63	7.27
	Follow up Proxy	89	16.55	42.55	31.87	6.43
<b>TOTAL</b>	Baseline	244	14.08	51.00	32.62	7.16
	Follow up	273	13.00	46.09	32.45	6.56
<b>DID NOT</b>	Baseline	67	N/A	N/A	N/A	N/A
<b>COMPLETE</b>	Follow up	148	N/A	N/A	N/A	N/A

There are higher numbers of proxy measures completed at follow up than at baseline due to the use of proxy measures not being introduced until several sites had been completed at baseline. Table 17 summarises the QOL-AD scores for Carer Proxy (in this context referring to those measures completed by carers about the person living with dementia as opposed to proxy measures in Table 16 that were on behalf of the person living with dementia).

**Table 17:** Unadjusted mean values for the two treatment groups at the two assessment points for QOL-AD Carer Proxy

Quality of Life in Alzheimer's Disease (QoLAD) – Carer Proxy						
		N	Minimum	Maximum	Mean	Std. Deviation
<b>Control</b>	Baseline	27	14.18	46.58	35.60	7.46
	Follow up	31	21.00	45.50	35.33	6.98
<b>Intervention</b>	Baseline	19	17.73	42.55	32.33	6.41
	Follow up	13	17.00	39.00	33.01	5.76
<b>TOTAL</b>	Baseline	46	14.18	46.58	34.25	7.16
	Follow up	44	17.00	45.50	34.65	6.67
<b>DID NOT</b>	Baseline	276	N/A	N/A	N/A	N/A
<b>COMPLETE</b>	Follow up	379	N/A	N/A	N/A	N/A

As previously mentioned it was harder than expected to recruit carers to the study. Of the measures completed 7 were completed by family carers whilst 61 were completed by professional carers.

Table 18 shows the mean scores for both the control and intervention group in relation to the IDEA questionnaire. It can be seen from the figures that only small numbers of these questionnaires were completed as they appeared to be too cognitively complex for most participants. All proxy measures of the IDEA questionnaire were completed by family carers as it was not felt appropriate to ask staff to comment on whether they were upholding resident's Human Rights. The possible range of scores on the IDEA questionnaire was 29 to 87. A higher score on the IDEA questionnaire reflects less satisfaction with regards to Human Rights. The IDEA questionnaire is included in Appendix 2.

**Table 18:** Unadjusted mean values for the two treatment groups at the two assessment points for the IDEA questionnaire

		IDEA				
		N	Minimum	Maximum	Mean	Std. Deviation
<b>Control</b>	<b>Baseline</b>	42	29.00	63.37	36.81	6.41
	<b>Follow up</b>	25	29.00	56.79	39.13	7.02
	<b>Base SR</b>	40	29.00	63.37	36.90	6.42
	<b>Follow SR</b>	21	29.00	56.79	38.88	6.89
	<b>Base Proxy</b>	2	29.00	41.00	35.00	8.49
	<b>Follow Proxy</b>	4	33.14	53.00	40.48	8.66
<b>Intervention</b>	<b>Baseline</b>	28	29.00	53.17	35.33	6.01
	<b>Follow up</b>	17	29.00	54.22	36.41	7.01
	<b>Base SR</b>	27	29.00	53.17	35.37	6.12
	<b>Follow SR</b>	15	29.00	54.22	35.91	6.92
	<b>Base Proxy</b>	1	34.37	34.37	34.37	N/A
	<b>Follow Proxy</b>	2	33.64	46.65	40.15	9.20
<b>TOTAL</b>	<b>Baseline</b>	70	29.00	37.00	36.22	6.25
	<b>Follow up</b>	42	29.00	56.79	38.03	7.06
<b>DID NOT</b>	<b>Baseline</b>	260	N/A	N/A	N/A	N/A
<b>COMPLETE</b>	<b>Follow up</b>	391	N/A	N/A	N/A	N/A

Table 19 shows the mean scores on the care plan audit for both the control and intervention group at both baseline and follow up. The minimum possible score on the Care Plan Audit was 0 and the maximum was 86. A higher score implies a more detailed, person centred care plan. The Care Plan Audit tool is included in Appendix 2.

**Table 19:** Unadjusted mean values for the two treatment groups at the two assessment points for Care Plan Audit

		Care Plan Audit				
		N	Minimum	Maximum	Mean	Std. Deviation
<b>Control</b>	<b>Baseline</b>	107	24.00	60.00	41.69	7.24
	<b>Follow up</b>	136	21.00	63.00	44.38	8.01
<b>Intervention</b>	<b>Baseline</b>	112	24.00	59.00	43.82	6.58
	<b>Follow up</b>	127	27.00	61.00	47.20	6.43
<b>TOTAL</b>	<b>Baseline</b>	243	21.00	63.00	43.19	7.78
	<b>Follow up</b>	239	24.00	61.00	45.62	6.70

The maximum possible score on the knowledge quiz was 13 and the minimum was 0. Follow up measures were not completed with the control group. A copy of the knowledge questionnaire is included in Appendix 2. Table 20 summarises the mean values on the Knowledge quiz for control and intervention group and both baseline and follow up.

**Table 20:** Unadjusted mean values for the two treatment groups at the two assessment points for the Human Rights Knowledge Quiz

		Knowledge Quiz				
		N	Minimum	Maximum	Mean	Std. Deviation
<b>Control</b>	<b>Baseline</b>	32	6.00	11.00	9.00	1.34
	<b>Follow up</b>	N/A	N/A	N/A	N/A	N/A
<b>Intervention</b>	<b>Baseline</b>	36	5.00	12.00	9.31	1.41
	<b>Follow up</b>	43	6.00	13.00	11.40	1.58
<b>TOTAL</b>	<b>Baseline</b>	68	5.00	12.00	9.16	1.38
	<b>Follow up</b>	43	6.00	13.00	11.40	1.58

The maximum possible score on the attitude quiz was 12 and the minimum was 60. Follow up measures were not completed in the control group. A copy of the attitude questionnaire is included in Appendix 2. Table 21 shows the mean scores for each group on the attitudes questionnaire.

**Table 21:** Unadjusted mean values for the two treatment groups at the two assessment points for the Human Rights Attitude Questionnaire

		<b>Attitude Questionnaire</b>				
		N	Minimum	Maximum	Mean	Std. Deviation
<b>Control</b>	<b>Baseline</b>	41	40.00	60.00	51.24	5.18
	<b>Follow up</b>	N/A	N/A	N/A	N/A	N/A
<b>Intervention</b>	<b>Baseline</b>	58	40.00	60.00	49.78	4.32
	<b>Follow up</b>	57	44.00	60.00	53.02	4.11
<b>TOTAL</b>	<b>Baseline</b>	99	40.00	60.00	50.38	4.73
	<b>Follow up</b>	57	44.00	60.00	53.02	4.11

When the full dataset was examined for the QOL-AD the additional covariate included for self-report/proxy was statistically significant indicating that there was a difference between the data collected via self-report and proxy. Therefore, as per the analysis plan the data has also been split to investigate the models on the self-report and proxy data separately.

There was no indication of the interaction between time and allocated group being significant.

All outcomes were assessed for normality within the model fitting, the data for the proxy QOL-AD exhibited some trends towards non-normality and a cubic transformation was applied. Tables 22 and 23 summarise this data.



**Table 22:** df, F and p values for the fixed factors of the fitted models for the primary outcome QOL-AD and subsequently split for self-report and proxy

Source	Numerator df	Denominator df	F	p
<b>Full dataset</b>				
Intercept	1	16.22	7136.13	< 0.001
Status QoLAD	1	295.29	77.20	< 0.001
Time	1	274.35	0.09	0.761
Group	1	16.51	3.63	0.074
Time*Group	1	266.73	0.001	0.980
<b>Self-report data</b>				
Intercept	1	14.67	3692.15	< 0.001
Time	1	73.02	1.10	0.297
Group	1	14.88	0.23	0.641
Time*Group	1	74.90	0.04	0.836
<b>Proxy data</b>				
Intercept	1	13.04	4596.29	< 0.001
Time	1	177.18	1.90	0.170
Group	1	13.53	4.35	0.056
Time*Group	1	181.67	0.02	0.886

**Table 23:** df, F and p values for the fixed factors of the fitted models for the primary outcome

	Mean difference	df	SE	LCI	UCI	Effect size
<b>Complete dataset</b>						
<b>Group</b>	1.48	16.505	0.655	-0.28	3.24	0.03
<b>Self-report data</b>						
<b>Group</b>	0.449	14.879	0.664	-2.15	3.05	0.10
<b>Proxy data</b>						
<b>Group</b>	1.785	17.678	0.548	-0.33	3.90	0.14

### Secondary outcome measures

There was no evidence of a significant difference for the allocated group for either of these outcomes. The IDEA demonstrated trends towards non-normality and a square root transformation was applied to rectify this. There was no indication of time and allocated group being significant – this is displayed in Table 24.

**Table 24:** df, F and p values for the fixed factors of the fitted models for the secondary outcomes, IDEA and CPA

	Mean difference	df	F	p	SE	LCI	UCI	Effect size
<b>Carer Quality of Life in Alzheimer's Disease (QoLAD)</b>								
Group	11.576	6.440	1.850	0.219		31.587	38.814	0.04
<b>IDEA</b>								
Group	-0.002	9.758	1.130	0.313		34.492	39.288	-0.08
<b>Care Plan Audit</b>								
Group	1.960	18.138	1.149	0.298	1.041	42.580	46.930	0.12

For the Care Plan Audit there was a significant effect of time,  $F_{1,220.19}=22.093$ ,  $p<0.001$ .

Due to the limited number of family carers present providing data for the IDEA Proxy, WEMBS and ZBI it was not possible to analyse these with any stability using a linear mixed model. Descriptive statistics have been included in appendix 3.

There was a statistically significant difference in both knowledge ( $t(30)=-7.02$ ,  $p<0.001$ ) and attitudes questionnaire ( $t(55)=-53.87$ ,  $p<0.001$ ) demonstrating an increase in both immediately post training. These figures are summarised in Table 25. The difference between the intervention and control group at baseline was also assessed and no statistically significant difference was seen ( $t(66)=-0.914$ ,  $p=0.364$  for the knowledge questionnaire,  $t(97)=1.532$ ,  $p=0.129$  for the attitude questionnaire). Given the short time span and no control data over the same period the interpretation of these results must be careful but there is some evidence of an improvement in these domains post-training.

**Table 25:** The paired sample t-test results for the Knowledge and attitudes questionnaires completed pre and post training

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Human Rights Attitude Questionnaire baseline - Human Rights Attitude Questionnaire follow up	-3.00	3.82	.51	-4.02	-1.98	-5.87	55	< 0.001
Human Rights Knowledge Questionnaire baseline- Human Rights Knowledge Questionnaire follow up	-2.13	1.69	.30	-2.75	-1.51	-7.02	30	< 0.001

## **Additional analyses**

### **Additional co-variables**

The additional covariates included into the linear mixed models were age, gender, (DCM), dementia type and whether a person has a carer or not (Carer\_YN).

For the QOL-AD measure none of these co-variables were statistically significant. For the IDEA, there was an indication that gender was statistically significant ( $F_{1,70.43}=5.96$ ,  $p=0.02$ ). Results of all these models are given in Appendix YY.

For the CPA the additional covariate added into the model was the completion of the QOL-AD (self-reported, not completed and proxy-completed). This was statistically significant indicating that there were differences in the CPA scores.

### **Variation of follow up**

One of the sites had only an 11 week follow up period rather than the 16 week period stipulated. Allowing the time difference to feature in the linear mixed model by adjusting the time variables to have three levels (Baseline, 11 week follow up and 16 week follow up) did not change any of the statistical interpretation of the models. Therefore it was deemed that there was no impact of this difference in follow up time on the outcomes observed.

### **Intraclass Correlation Coefficient**

The intraclass correlation coefficient was calculated for the QOL-AD. The difference between pre and post results was calculated first. Then the variance component was calculated with site as a random effect. Using this method the intraclass correlation coefficient was found to be 0.09.

### ***Dementia Care Mapping***

At each site the ME scores for participants were grouped together to give an overall score at baseline and follow up. The scores were then separated into intervention and control and an overall average of the ME scores were calculated. The results of the mapping exercise are displayed in Table 26.

**Table 26:** Average mood and engagement scores for intervention and control at baseline and follow-up

	ME scores	Baseline	Follow-up
<b>Intervention</b>	+5	0.8%	0%
	+3	39.3%	29.3%
	+1	57.8%	69.5%
	-1	1.8%	1.1%
	-3	0.3%	0.1%
	-5	0%	0%
<b>Control</b>	+5	1.4%	0.1%
	+3	34.1%	28%
	+1	62%	69%
	-1	2%	2.5%
	-3	0.5%	0.4%
	-5	0%	0%

In accordance with one of the objectives of the study, it was hypothesised that you would see an increase in ME scores at sites where training had been delivered. However, the table above highlights that regardless of whether sites were intervention or control there was no improvement in ME scores. Additionally, for the majority of sites there was a decrease from baseline to follow up.

## Health Economics

### *Outcome measures*

Descriptive statistics for the outcome measures are shown in Table 27 for baseline, and Table 28 for follow-up. As can be seen, completion of the carer measures (ZBI and WEMWBS) were low, precluding any further analysis.

The mean EQ-5D self-report score at baseline was 0.74 (s.d. 0.267), which is similar to the mean UK population score of 0.78 (s.d. 0.26) for the age group of 65-74 year olds. We note that proxy scoring of the EQ-5D was much lower (mean 0.35, s.d. 0.337), which is a similar finding to other studies involving proxy reporting for people with dementia (cite REMCARE report). The lower proxy scores of the EQ-5D were driven by lower ratings in the self-care item.

**Table 27:** Outcome measures at baseline (all available participants split by group)

Control	N	Minimum	Maximum	Mean	Std. Deviation
ASCOT Total	45	.22	1.00	.8396	.16536
ASCOT-proxy Total	60	.46	1.00	.7848	.15177
EQ-VAS	40	50.0	100.0	75.350	15.8802
EQ-5D Total	56	-.016	1.000	.72641	.265127
EQ-VAS proxy	93	10.0	100.0	61.452	22.4768
EQ-5D proxy Total	95	-.349	1.000	.35873	.329315

WEMWBS Total	3	41.0	47.0	44.000	3.0000
ZBI Total	3	28.000	37.000	33.03333	4.593836
<b>Intervention</b>	<b>N</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>Std. Deviation</b>
ASCOT Total	40	.74	1.00	.8870	.09504
ASCOT-Proxy Total	87	.16	1.00	.8182	.18658
EQ-VAS	31	50.0	100.0	81.935	17.4010
EQ-5D Total	45	-.043	1.000	.76378	.271051
EQ-VAS Proxy	109	5.0	100.0	63.789	17.6363
EQ-5D Proxy Total	107	-.371	1.000	.34907	.345178
WEMWBS Total	3	48.0	52.0	50.333	2.0817
ZBI Total	3	8.381	34.000	19.71429	13.062209



**Table 28:** Outcome measures at follow-up (all available participants split by group)

<b>Control</b>	<b>N</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>Std. Deviation</b>
ASCOT Total	43	.24	1.00	.8451	.17115
ASCOT Proxy Total	88	.2	1.0	.793	.1692
EQ-VAS	38	20.0	100.0	74.868	21.7009
EQ-5D Total	53	-.016	1.000	.74428	.255365
EQ-VAS Proxy	128	10.0	100.0	59.414	21.1353
EQ-5D Proxy Total	128	-.536	1.000	.34233	.344512
WEMWBS Total	0				
ZBI Total	0				
<b>Intervention</b>	<b>N</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Mean</b>	<b>Std. Deviation</b>
ASCOT Total	27	.09	1.00	.8522	.19902
ASCOT Proxy Total	88	.4	1.0	.824	.1609
EQ-VAS	24	.0	100.0	73.125	28.2386

EQ-5D Total	33	-.077	1.000	.66467	.321907
EQ-VAS Proxy	108	10.0	100.0	61.861	17.5395
EQ-5D Proxy Total	105	-.429	1.000	.42918	.327650
WEMWBS Total	2	38.0	48.0	43.000	7.0711
ZBI Total	2	10.000	30.381	20.19048	14.411510

### Service use

Most health and social care contacts at both baseline and follow-up were home visits. The mean number of GP and community nurse contacts were highest. A more detailed breakdown of the community and hospital based services used within a 4 month period is available in appendix 3.

### Medication

At baseline, medication records were collected for 254 participants. Medications were categorised according to the Prescription Cost Analysis categories, and are shown in Table 29. The most frequently prescribed category was for the Central Nervous System, which includes dementia medication, analgesics, antidepressants and hypnotics and anxiolytics. 101 out of the 254 participants for whom information was available for were prescribed a dementia drug. Eight of these people were prescribed more than one dementia drug.

**Table 29:** Numbers of prescriptions by category for 254 participants at baseline

Category of Medication	Number of prescriptions at baseline	Number of prescriptions at follow up
Anaesthesia	5	1
Cardiovascular System	377	337
Central Nervous System	722	651
Ear, nose and oropharynx	3	1
Endocrine system	105	102
Eye	29	17
Gastrointestinal System	297	266
Infections	29	25
Malignant disease and immunosuppression	1	5
Musculoskeletal and joint diseases	19	13
Nutrition and blood	211	156
Obstetrics, gynaecology and urinary tract disorders	16	10
Respiratory system	57	31
Skin	32	8
No medication	7	6
Sterile water	1	0
<b>Total</b>	<b>1911</b>	<b>1602</b>

A more detailed breakdown of the medications prescribed is available in appendix 3.

## Cost of the intervention

There were no intervention design costs as the intervention was developed prior to this study taking place. Nine training sessions were delivered on-site to staff. Staff receiving training at hospital sites ranged from NHS Band 3 Support Workers to NHS Band 7 ward managers. Staff receiving training at care home sites ranged from care home managers to care home assistants. Each training session lasted 5 hours and was delivered by a NHS Band 8a trainer. Sites were given two copies of the training manual and 12 copies of response booklets. In total, 71 members of staff were trained at a cost of £7,157, or £101 per staff member. The intervention costs are summarised in Table 30.

**Table 30:** Cost of the intervention

Site	Cost of staff time	Travel costs for trainer	Training materials cost	Administration costs	Total cost	Number of staff trained	Cost per staff member trained
901	£473.35	£44.58	£43.46	£29.83	<b>£591.22</b>	8	£73.90
904	£880.10	£19.81	£43.46	£29.83	<b>£973.20</b>	11	£88.47
904 (second visit)	£880.10	£19.81	£43.46	£29.72	<b>£973.09</b>	11	£88.46
910	£591.25	£24.77	£43.46	£44.58	<b>£704.06</b>	6	£117.34
912	£564.00	£14.86	£43.46	£14.92	<b>£637.24</b>	6	£106.21
913	£684.85	£44.58	£43.46	£44.58	<b>£817.47</b>	6	£136.25
916	£1,040.25	£29.72	£43.46	£29.72	<b>£1,143.15</b>	11	£103.92
917	£507.45	£19.81	£43.46	£14.92	<b>£585.64</b>	7	£83.66
919	£584.90	£59.44	£43.46	£44.58	<b>£732.38</b>	5	£146.48
<b>TOTAL</b>	<b>£6,206.25</b>	<b>£277.39</b>	<b>£391.14</b>	<b>£282.67</b>	<b>£7,157.45</b>	<b>71</b>	<b>£100.81</b>

## Qualitative Results

### Staff Decision Making Interviews

The thematic analysis identified 21 themes from the combined data set (301 interviews).

The interviews were then reanalysed to identify the frequency of each decision making strategy within the data and for each group (i.e. control baseline, control follow up, intervention baseline, intervention follow up) – this information is shown in Table 31.

There were similar total numbers of decision making strategies in each group. It can be seen from the table that the most common theme in all groups in relation to decision making strategies was working as a team or consulting with other staff. This was followed by hierarchical decision making where responsibility for making the decision was passed over to another member of staff who was considered to be of a higher position and therefore more able to make a decision. It can be noted however that there was a drop in the reliance on hierarchical decision making in the intervention group (although it still remained the second most popular strategy for this group).

Although there are some variations across the groups in relation to decision making strategies, and it is acknowledged that any conclusions drawn would need to be cautious, it does appear that there are some differences in the intervention group at follow up. Staff in this group were less likely to cite common sense as a strategy that they would employ to help them make decisions whereas this strategy actually increased amongst the control group. The intervention group were also less likely to cite fear, the need to follow rules and 'it's not my job' as methods by which to make a decision. The intervention group were also more likely to explicitly mention Human Rights (such as dignity, respect, positive risk taking) and person centred care. It is perhaps not surprising that the intervention group were more likely to mention specific Human Rights based approaches given the training they had undertaken and their knowledge at this point that the site was involved in a Human Rights study but the translation of this into person centred principles which were not explicitly included in the training but which, it has been proposed, are closely linked to the application of a Human Rights Based Approach is interesting.

**Table 31:** The frequency of decision making strategies utilised by each group

Theme	Control		Intervention	
	Baseline	Follow up	Baseline	Follow up
Team work/ Talking to other staff	228	185	225	241
Hierarchical decision making	191	222	192	147
Previous Experience	87	83	66	45
Speak to the family	84	95	104	124
Knowledge of the person	69	65	86	89
Using pre existing documents	68	75	98	84
'It's in their best interests'	67	60	57	61
Using legislation e.g. DOLS, MCA	65	49	42	52
Observe/ Monitor	64	44	44	57
Common Sense	58	81	65	27
Training	58	47	29	28
Share Information	28	33	20	33
Speak to the person	24	69	40	48
Empathy	21	21	14	22
Human Rights	25	17	20	49
Policy and Procedure	19	26	28	18
It's not my job	19	22	20	12
Fear	16	19	10	1
Person Centred Care	15	19	15	43
Follow the rules	9	10	15	4
<b>Total</b>	<b>1223</b>	<b>1245</b>	<b>1190</b>	<b>1183</b>

## Follow up Interviews

Follow up interviews were offered to all intervention sites that completed the training. Some sites were unable to accommodate the interviews due to changes in management and lack of staffing. In total 6 of the 8 sites who completed training completed interviews designed to look at acceptability and effectiveness of the intervention. Interviews were conducted on an opportunistic basis and included staff who had attended the training, staff who had not attended the training and where possible the unit manager. The interviews were completed by a research assistant (not the same research assistants who had visited the sites to collect data) and a member of the PPI reference group; either a person living with dementia or a carer.

On average 4 staff per site were interviewed. Of the 8 sites who had completed the intervention 4 had a new manager at these interviews. Table 32 shows the staff who were interviewed at each site and the percentage of staff trained who remained at the site at this point (approximately 6 - 10 months after intervention). Sites here are listed as 1, 2, 3 etc. so that they are not identifiable. Given that the information gathered at individual sites is later linked to management styles it was felt to be important to preserve anonymity of the sites.

**Table 32** : Follow up interviews

	Sites who completed follow up interviews					
	1	2	3	4	5	6
Staff Interviewed	4	4	4	3	6	3
Attended training	4	4	1	1	3	1
Did not attend training	0	0	3	2	3	2
Manager interviewed	No	Yes	Yes	No	Yes	No
% of staff trained still at site	Unknown	86%	67%	Unknown	100%	Unknown
Manager still in post	Yes	Yes	No	No	Yes	No

Three themes were derived from the data related to the use and acceptability of the intervention. It is fully acknowledged that the questions posed to staff guided them to discuss the acceptability and effectiveness of the intervention and that the themes generated are therefore not surprising. The overarching themes and subthemes related to acceptability and effectiveness are summarised in table 33 and described in more detail below.

**Table 33:** Themes from the follow up interviews at intervention sites

Theme	Sub-theme
Accessibility of the intervention	Simple Time consuming Similar to current practice Management support
Benefits to the residents	Increased knowledge about residents Improved care plans Increased trust between service users and staff
Benefits to staff	Access to training Increased knowledge about residents Feeling like they were behaving in a less institutionalised way Changed thinking

### ***Accessibility of the intervention***

In general staff found that the training and assessment tool were extremely simple and understandable:

*‘The tutor lady was fab. Simple’*

*‘The information that was given. The way it was laid out as well. It was explained simply in layman’s terms. The way we understand it. When someone comes in and talks to you the likes of solicitors they talk and I go listen just tell me as it is and that is*



*what was good about the kit. It was in our terms. There was no complex words. Nothing that we didn't understand.'*

It was noted that the 'Getting it Right' assessment tool could be time consuming to complete and this had implications for completion of the tool:

*'...it is such a busy unit. It is hectic to try and fit the extra stuff in'*

However, there was also a sense that completion of the tool was worth the effort:

*'It does take quite a bit of time to gather all the information, from the individual. Learning about the individual and what they like especially if they can't always tell you. And meeting family members and being able to have those conversations because sometimes they just want to off load what they have been going through. So it is quite timely but that is fine because it is so worthwhile because it allows you to collect so much data basically off the patient about what is important and how we are going to make their stay better that it is worth while taking the time over it.'*

Some sites reported that they felt that the intervention was similar to their current practice, particularly related to life story work being routinely carried out:

*'We were partly doing it anyway and this was just a slight improvement on what we were already doing.'*

Comments were made, both positive and negative, related to the level of management support for the intervention and the impact this had on the intervention being applied:

*'But I am the one who gave the staff the support and said how are you getting on, have you been through it? We supported each other'*

*'No, they just got put in the office and we never got around to it'*

### ***Benefits to the residents***

There were several potential benefits for residents identified in the interviews. It was recognised that the completion of the 'Getting it Right' assessment tool ensured that there was more information readily available about each resident and that this had an impact on

the care and treatment that the residents received. They also emphasised the positive involvement of the family in gathering this information:

*'Because you are asking the family as well they are surprised at oh how do you know that about me. So they're I feel that they are more involved. Rather than just plodding along everyday it is making them feel involved as well. You are all working collectively then. All singing under the same umbrella. If you talk about something individual to them. It makes them think more as well. It makes them feel more important knowing their background.'*

Similarly, staff highlighted that the completion of the 'Getting it Right' assessment tool improved care plans and that translated into more individualised care:

*'I went through the care plan in great depth and found out bits and pieces and I spoke to the family to find out more and got bits. We got books and music because we found out things this lady used to do. I do find some people do sit and do not talk as such where I am happy to just sit and talk and eventually she will talk back.'*

This continued even when the staff members were no longer directly using the 'Getting it Right' assessment tool:

*'when the staff are formulating care plans the information is there. We got given your care plans but we don't have that paperwork here but now the content of the care plans reflect that information. There is a lot more information. A lot more making sure we have background information. They get more involved with family and friends to get as much information about that individual.'*

There was also a sense that completing the assessment tool and gathering the information increased trust between residents and staff:

*'The main things is that the service users trust you. Because they are frightened. Dementia is a frightening thing. So they have got to have trust and if people can come along and say this is Jack he likes this he likes that without having to explain to 24 different staff. I think it helps build trust and it helps build that professionalism that*

*they feel they can trust you. That they are not every 5 minutes having to explain who they are. Makes they feel understood and cared for.'*

And that in turn this facilitated a more empathic approach to care:

*'The books that we filled in we have used them on a daily basis. Use them to support people. I feel like I can empathise more. We have one lady who has bad dementia and we understand what she needs and what she wants. She folds tissues up and she thinks that is money. (We) understand why they do something that might seem strange to us. She just folds them up and she has them in her hand bag she gives them to you. And you take them off her and she feels 1000 times better.'*

### **Benefits to staff**

It was worrying that staff felt that this training, which was not designed to be core training in dementia care, was filling a need for training for members of staff, particularly those who were unqualified:

*'The support workers do not often get training and they feel that they have benefitted from the training. It has made them think about things.'*

This resulted in many staff being extremely positive about the training they received:

*'I just remember it all being really exciting. I was buzzing'*

And the impact it had on them and their ability to do their job:

*'And it did make a massive difference to our job. A massive difference.'*

It was highlighted that getting to know residents better, and having a greater understanding of their past helped staff feel closer to them and in turn improved their working lives:

*'Like one guy who absolutely loves chatting and he will chat to you all day long. The minute you mention [Name] his eyes just light up. Because that is all he knows and remembers. So we have got history on the computer, so we have looked up things that involve him. You know reading into things like that so you can talk to him*

*properly and his eyes light up, it is amazing. Going back like more like information more than anything else, getting more background on them and their interests. It has had a big impact on myself.'*

*'One lady we have got different pictures in her room now, because I found out a lot more about her.....That made me feel so happy though because I felt so much closer to her.'*

Staff commented that the training in particular had changed the way that they thought about situations and encouraged them to think of things through a Human Rights lens. Considering each person as a human being with Rights:

*'I just think that people think they know the Human Rights Act but it is in terms of their own situation, rather than how it translates to everyone else because I have never. It is always a given the right to have a choice and all those things but it is not necessarily so. And I think that institutions and care staff tend to think that they are the rules and if you live in a particular place meal times have always got to be at time and if you don't want what is on the menu you don't eat and it still goes on. If you don't eat it you won't have anything else. Well that is not right. It certainly shouldn't be like that today. So with this training it makes staff realise we are only part of a bigger world and everyone has got a right.'*

This also facilitated a more compassionate approach staff and potential 'mistakes' they may make by helping people to understand the reasons behind behaviour:

*I think people's attitudes changed during the training. People should only be vilified if they know what they are doing is wrong. Sometimes people come working in a place like this and they have got no experience and they do just see tasks. They do just see 18 baths or 18 toilets. That is all they see. They focus on that and it is easy to forget the person. I just think that with this it - makes you think what have I done? I have done that in the past. Would I do it again? No. Because I have seen it from a different perspective.'*

This resulted in staff feeling like they were behaving in a less institutionalised way and responding more to the needs of the person. In this way the training and adoption of the

approach provided freedom to act in way that the staff fundamentally felt were right but had previously been criticised:

*‘In a way it has taken pressure off. In as much that nobody expects everybody to be in their clothes by ten o clock. I they are not in their clothes by 10am there is a blooming good reason for it. And people go along with that. You know it is less of an institutionalised way. Because it is about what fits in with the service user, not what fits in with the programme on the ward. There is more awareness and like I say it has created a bit more freedom for us.’*

### **Suggestions for Improvements**

During the interviews staff were also asked to comment on potential improvements to the approach. The following suggestions were made:

- More staff from each unit trained so that knowledge could be shared and the whole team appreciate the approach.
- More booster sessions to cement learning
- Digitalising the ‘Getting it Right’ assessment tool to make it easier to use

### **Management Style**

As management support was such a key feature in many of the interviews the data gathered was subsequently analysed using a deductive approach and mapped on the characteristics from Bass and Alvolio’s <sup>[85]</sup> management style. It is acknowledged that the information gathered in this way was not specifically gathered about management style and any conclusions made are tentative.

Bass <sup>[84, 86]</sup> describes *Transformational Leadership* as ‘moving the follower beyond immediate self-interest’ and *Transactional Leadership* as ‘the exchange relationship between leader and follower to meet their own self-interests, to take the form of contingent reward in which the leader clarifies for the follower through direction or participation what the follower needs to do to be rewarded for the effort’. The model breaks down each leadership style into different characteristics. Transformational leadership is comprised of; intellectual

stimulation, individualised consideration, charisma and inspiration. In comparison transactional leadership is comprised of leadership styles such as; passive management by exception (i.e. waiting for problems to arise before taking corrective action), active management by exception (i.e. monitoring performance and taking corrective action if the follower fails to meet standards), laissez-faire and contingent reward. Table 34 outlines the characteristics associated with both Transformational and Transactional Leadership styles.

**Table 34:** Characteristics of Transformational and Transactional leadership styles

Leadership Style	Characteristics
Transformational Leadership	Intellectual Stimulation
	Individualised Consideration
	Charisma and inspiration
Transactional Leadership	Passive management by exception
	Active management by exception
	Laissez-faire
	Contingent reward

It has been suggested <sup>[85]</sup> that a transformational management style can enhance commitment, involvement, loyalty and performance and help individuals deal with stress. In contrast a transformational management style is likely to induce stress in staff.

When the data from the interviews was deductively analysed in line with the management styles outlined above certain patterns were noted. At two sites (2 & 5), more codes were identified related to a transformational management style, in particular relating to two characteristics; intellectual stimulation and individual consideration.

Intellectual Stimulation is characterised as ‘ the degree to which a manager encourages others to be creative in looking at old problems in new ways, create an environment that is tolerant of seemingly extreme positions and nurture people to question their own values and beliefs and those of the organisation’ <sup>[86]</sup>. Four codes appearing to relate to intellectual stimulation were identified within the interviews:

1. Managers actively seeking ways for the team to improve.

*‘We heard about the study from another care home that is actually a dementia care home and we sort of when we asked could we join. We were desperate to be involved.’*

2. Manager’s openness to criticism.

*‘If I have got problems in my home can you tell me. If you can do something better that is great. It effects everybody.’*

3. Managers showing evidence of problem solving and adapting the Human Rights based approach and ‘The Getting it Right Tool Kits’.

*‘They still use the books, but the pages have been printed and put on the walls in the bedroom. This makes them much easier to use for staff and patients.’*

4. Manager’s actively sharing and disseminating information about a Human Rights Based Approach.

*‘Well basically we just got an e-mail saying listen we are going to start trying this see if it works see if it is helpful and they brought in the paper work and went through it with us and we just started implementing it on the ward.’*

Individual consideration is characterised as helping others to develop themselves, letting other know how they are doing and giving personal attention to those who seem rejected. Two codes were identified that related to this aspect of transformational style.

1. Managers being active in motivating staff to attend training and to utilise the assessment toolkits.

*'But I am the one who gave the staff the support and said how are you getting on have you been through it. We supported each other. Do you understand it? I think at first they said we just have to concentrate on the red things and that was it you can leave the others. And I said it is not that you can leave them it is just that initially when they come into the building they are the things you need to give them safe care but everything is important. And they were like okay we will carry on doing it. But we worked together with that one. I was integral. I am really lucky with my staff.'*

## 2 'Understanding staff' and their motivations

*'For them to have volunteered for it nobody ever volunteers for training. They would be reluctant at first. If I hadn't driven it would they have done it, probably not? I do that with any of the training because if you didn't they would say if you can't be bothered they can't be bothered. Put it that way. I do think someone has to give them that drive. If you explain it to them they are like okay.'*

At two sites (1 & 3) there were more codes relating to a transactional management style. These mainly fit into the laissez-faire style of management though one code fit into the passive management by exception category.

Laissez-faire is a manager who is content to allow staff to do their own thing. Someone who is; content for staff to work the same way always, happy to do whatever and asks no more of staff than what is essential. Four codes relating to laissez faire style of management were identified within the interviews.

### 1. Lack of management support and encouragement

*'I think it covered every aspect but I don't think we have enough support and staffing levels. A lot of staff on the floors.'*

### 2. Failure in communication between past and present management

*'I only heard about the study from this evaluation.'* (New Manager)

### 3. Failure in communication to staff



*'No they just got put in the office and we never got round to it. I don't know where they are because our manager has left.'*

4. A lack of resources being used a reason not to make changes

*'Always resources stop me from doing these things. You always want more than what you have got. I don't feel as though profit and care are good bedfellows really. When certain things are counted and continent aids are counted that does not lead to respect or rights. That is a major issue.'*

Passive Management by exception is described as only dealing with an issue if it comes up. A manager who is happy if staff are; meeting agreed standards, as long as things are working and as long as individuals know the standards. One code was identified relating to this style of management.

1. Passive support

*'We didn't use it but I can't see what would prevent us. I was wanting to have a word with the manager about it rather than just go ahead off my own back. I would rather ask, check with the manger to check that it is okay.'*

At sites where there were more descriptions of managers being active or transformational in adopting a Human Rights based approach, staff describe utilising the 'Getting It Right Toolkits', they felt generally more supported and understood and experienced the worth of prioritising them to provide person centred care. Staff provided descriptions of improved service user wellbeing, engagement and increased trust with them and their families.

At sites where there were more themes related to transactional management there was less uptake of the approach. Although staff reported being excited about the approach; 'I just remember it all being really exciting. I was buzzing' lack of management support resulted in the approach not being applied; 'No they just got put in the office and we never got round to it'.

## Chapter 4 - Discussion and conclusions

### Summary of Findings

The findings of the study are very clear. There was no evidence that introducing this Human Rights Based approach improved the well-being of people with dementia or the quality of care in dementia inpatient wards or care homes. The delivery of the training had the desired effect in that it significantly increased both knowledge about Human Rights and positive attitudes towards Human Rights. Similarly there was a shift in decision making strategies in the intervention group at follow up with this group relying less on 'common sense' to make decisions and talking more explicitly about using Human Rights concepts, such as dignity, respect, least restrictive practice and positive risk taking, and person-centred care to influence choices. However, neither of these factors translated to increased quality of care or reported well-being of people living with dementia.

There was an improvement in the quality of care plans at follow up but group was not a factor, i.e. there were improvements in both the control and intervention group. This suggests that it was the process of care plans being monitored that had an impact on the quality of care plans rather than the intervention. Similarly, as there was no difference in care provided or reported well-being as a result of improved care plans it could be inferred that what people are getting better at is writing person centred care plans as opposed to delivering person centred care. People who completed the QOL-AD had significantly better care plans than people who did not. This was most apparent when a Proxy QOL-AD had been completed. Those who had no QOL-AD completed had the worst quality care plans. Although there has previously been research into how a good quality care plan can improve the care people receive<sup>[87]</sup> there is limited work on what influences the development of a good quality care plan. It may be in this situation that the process of completing a QOL-AD about an individual prompted the staff member to update their care plan with relevant information. If this were the case it would highlight the importance of staff feeling that they had responsibility for getting to know specific residents in developing good quality care plans. There has at some sites been a move away from people having a key worker to

acknowledge the fact that all staff need to be able to interact with all residents but this may be diluting the feelings of responsibility in relation to care planning.

Men reported significantly higher levels of Human Rights violations on the IDEA questionnaire. Given the numbers collected and the fact that there appeared to be a floor effect on the questionnaire (with most participants reporting no or extremely limited Human Rights violations) it may be that this is not really a clinically significant finding. It could however reflect several of the characteristics of care settings that were identified in this study. During the interviews staff were asked to identify issues that they found challenging in their daily work. The most common theme was related to aggression and challenging behaviour. Whilst aggression and challenging behaviour is not only related to men this was identified as a particular issue. Trying to manage this difficult situation, which many staff report feeling unequipped for, may result in practices that could undermine an individual's Human Rights such as restraint, seclusion and over reliance on medication <sup>[88]</sup>. Similarly, it was clear from the demographics that the majority of staff providing care were female (67.4%). This may have had an impact on issues of privacy and dignity in relation to issues such as personal care.

## **Comparison to pilot**

The approach was initially piloted on Acorn ward in Mersey Care NHS Foundation Trust. It was well adopted and has been used by that site since 2012. During a recent CQC visit <sup>[89]</sup> the approach was praised stating; 'we saw that this had an impact on the frontline, with the implementation of a Human Rights Based Approach. This involved the development of a person centred assessment tool, which incorporated the values of Human Rights law' (page 12) and was it was highlighted as an area of good practice (page 15). During data collection the 'Getting it Right' assessment tool was seen at care homes that were in the control group due to the effective use of them on the inpatient ward and the routine sharing of them with care homes following discharge.

Reflection was therefore needed as to why uptake and adoption was so positive at the pilot site and yet was more difficult at intervention sites. It seems that there are several factors

which may have contributed to this difference. Several of the issues will be discussed further in this report. Staff members from the pilot ward were involved in the study from its outset including the design of the assessment tool and training package. As a result they may have felt more ownership for the approach and engaged more fully with it. All staff on the ward were trained in the approach together as there was Trust investment to support this and backfill was provided whilst the training took place. Staff in the current study suggested that it would have been better if more staff from each unit were trained as it would increase support and understanding. There was more support available during the pilot from a number of sources; the ward manager was fully supportive of the approach, advocated for it and allowed staff the time to complete the assessment tools, the Trust board was keen to see a Human Rights Approach adopted and provided support in relation to thinking about how this approach may replace other documentation, a lead person to ensure that the assessment tools were completed was identified by the ward and they oversaw its application, the trainers were readily available as they are at the same base to address any questions or queries. All of these factors may have contributed to better adoption at the pilot site.

## **Generalisability**

Baseline comparability of the two groups was good and characteristics reflected national statistics for people living with dementia. As such it is likely that a representative sample of the population of people living with dementia was recruited to the study. This would allow some degree of generalisability to the study. There are however a number of factors that could impact on this.

Although units were recruited from across the North West of England which is a relatively diverse area in relation to cultural and socioeconomic variables the participants involved in the study were less diverse, particularly in relation to ethnicity. Whilst there are not definitive figures for the ethnicity of the residents of the units the feeling from the research assistants was that they were overwhelmingly White British or White Irish. Similarly the vast majority of the staff (87.5%) were White British. This is unlikely to represent the general care home and inpatient population across the country.

It was acknowledged that there was considerable variation in what would be considered treatment as usual at each individual site. There were observed differences between sites in relation to the extent to which they adopted the approach and applied it to their work. There appeared to be some common themes to account for the difference in uptake such as management style but there are also likely to be idiosyncratic reasons for site uptake as well. As such it could be concluded that it may be of more utility to consider each site individually and tailor training and support to their particular requirements, as was done initially at the pilot site. This of course would have implications for the cost effectiveness of interventions.

## **Appropriateness of Outcome measures**

### **Well-being Measures**

As in previous studies <sup>[90]</sup> QOL-AD scores were lower when completed by a proxy than when completed by the person living with dementia. Previous studies have shown that agreement between proxy and self-report on the QOL-AD is higher when examining observable functions such as physical health and disability and relatively poorer for more subjective measures. It has also been shown that disagreement between proxies and self-report increases as the severity of dementia increased <sup>[91]</sup>. This is interesting in the context of this study as many of the people in this will have been living with a severe dementia. Similarly, previous work has found that whilst care home residents' reported QOL-AD scores correlate highly with levels of depression carer completed reports on the same measure correlate highly with level of dependence and behavioural issues <sup>[92]</sup>. As dementia progresses and people become more dependent proxies would therefore see those living with dementia as having a lower quality of life whilst there is evidence that levels of depression decrease as severe dementia progresses <sup>[93]</sup> and these same people may therefore rate their subjective quality of life as higher.

Self-reports of quality of life as measured by EQ-5D in this study were just as high as in the reported norms of people of a similar age without dementia. This again challenges the assumption that living with dementia negatively impacts on your self-reported quality of life. It is often assumed that the reason there is a difference between self-report and proxy

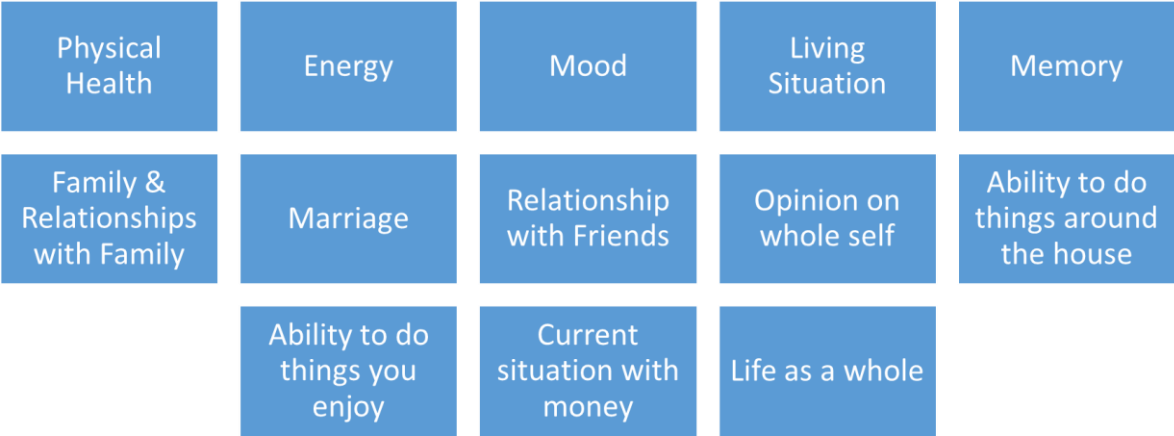
measures is because people with dementia lack the required insight into the impact of their condition to accurately report on their quality of life, but it is of course possible that proxies are unable to anticipate what it may be like to be living with dementia, particularly at later stages of the condition and as such may assume that quality of life will be poor. This may not be the reality for the person living with dementia. As such it is possible that self-report and proxy versions of the same measure are actually measuring different concepts. Pickard and Knight <sup>[94]</sup> identify two distinct proxy perspectives. The 'proxy-patient' perspective requires proxies to project themselves into the patient's internal state whereas the 'proxy-proxy' perspective is based on the proxy's judgement. They found that there tends to be less discrepancy between self-report and proxy when proxies are explicitly asked to adopt a proxy-patient perspective. There is also evidence that a proxy's own quality of life also impacts on their judgement <sup>[95]</sup>. It could therefore be questioned whether the use of proxy measures is appropriate to capture the subjective wellbeing of people living with severe dementia.

Whilst it has been suggested that the QOL-AD can be usefully completed with some people living with an MMSE score as low as 3 <sup>[96]</sup> (although it was originally suggested to have validity for people with MMSE scores over 10 <sup>[53]</sup>) it quickly became obvious that the majority of people living with dementia in the care homes and wards visited were unable to complete the measure even with assistance from skilled clinicians. This does not mean of course that it is not possible to elicit information about quality of life from people with more severe dementia <sup>[97]</sup> or that the team did not think that this was important. Indeed processes undertaken to elicit information from people at later stages of dementia is described earlier in this report <sup>[69]</sup>. Rather the use of the QOL-AD and the heavy reliance on proxy measures would bring into question whether it was an appropriate measure in this context. It may have been more useful to interview residents about their experiences of quality of life to elicit their views in a more naturalistic way.

Figure 7 summarises the domains of well-being covered by the QOL-AD. Given the items included in the measure it is worth considering why it would be expected that an intervention brings about change in these domains. The current intervention under investigation even if successful is not likely to change financial issues, ability to do things

around the house (although a person centred approach may encourage people to do more) or their marriage.

**Figure 7:** The constructs included in the QOL-AD



It may be more useful to look at other concepts which have been shown to have links to subjective well-being in dementia. Studies have indicated that care home residents with greater perceived control experienced significantly greater psychological well-being<sup>[98]</sup> e.g. perceived control regarding decisions about food, social activities, daily routines, privacy and sense of self. Similarly, a study of care home residents in Singapore<sup>[99]</sup> identified five predictors of quality of life in this population. Those factors were; comfort, dignity, food enjoyment, autonomy and security. Taken together this evidence would suggest that a more innovative measure designed to tap into concepts which actually matter to people living with dementia is needed if we are to accurately capture the subjective quality of life of people living with dementia, particularly more severe dementia.

***Dementia Care Mapping (DCM)***

Dementia Care Mapping was utilised as a way of observing the care provided at each unit. In particular the Mood and Engagement (ME) scores from each unit were compared at baseline and follow up in order to uncover any differences in care following the intervention. It is, however, important to be cautious about how much can be extrapolated from the overall

ME scores. Although DCM was originally created as a clinical tool to help improve the quality of care in clinical settings it has been used effectively to gain a more objective measure of service user wellbeing in a number of research studies<sup>[100]</sup>. There are potentially a number of factors, over and above the hypothesis of no change to care, that could have accounted for no change or a decrease in ME scores.

It was apparent that at baseline the majority of staff were not aware that the research was being carried out. Therefore at baseline several staff initially believed that they were being observed and were uncertain about the motives of the research assistants. As a result the levels of engagement with service users may have been influenced and potentially increased, particularly given that there was a clear finding within the study that care plans improved when people felt they were being monitored. Generally, at sites at follow up staff appeared to be more relaxed and it was felt that the behaviours observed were potentially a more accurate representation of the day-to-day care being provided. Given this finding it could have been useful to complete a pre baseline set of measures to allow the staff to become accustomed to being observed. This would of course have financial and time implications for the completion of the research.

Between baseline and follow up there were a large number of service users that had been discharged or passed away which at times resulted in different service users being observed. According to The Bradford Dementia Group<sup>[101]</sup> it is difficult to see change at separate time points when observing different people, therefore any changes that were hypothesised to occur at intervention sites may not be reflected in the overall ME scores.

Throughout the study it was noted that there was a large turnover of staff at sites from baseline to follow up. For a number of sites, there was a larger proportion of agency staff being employed at follow up compared to baseline. Although using agency staff is beneficial for meeting the desired staffing levels, it doesn't necessarily result in the continuity of care for service users. A lack of consistent staff could potentially be unsettling to some service users<sup>[102]</sup>. Taking this into consideration, this could be a potential factor as to why ME scores decreased at particular sites at follow up. In addition, at some sites agency staff were not being used hence staffing levels were extremely low. This is highly likely to have



impacted on ME scores as staff members were only able to meet the basic care needs of service users.

There were some sites in particular where the environment could have adversely impacted on ME scores. More specifically, the layout of the communal areas where mapping took place was not ideal. At times individuals could not be observed therefore giving them a behaviour category code of Q (Quit- individual wasn't in mapping area) for a number of time frames. At these particular sites, there are possibly several observations that could not be reported. Due to this the overall ME scores for these sites may not be a true representation as behaviours and levels of engagement could have been missed. This was of course true at both time points.

A general observation made during DCM was at follow up some service user's cognitive ability had declined and in some instances physical health had deteriorated. This could result in individuals not being able to or have difficulty participating in behaviours that generate higher mood and engagement scores. This may account for no change or a decrease in the overall ME scores obtained. However, given the client group involved this may be expected after a four month follow up.

During DCM a number of external organisations were observed at sites facilitating varied activities with service users. It was noted at one site in particular, at baseline activities were facilitated throughout the day however at follow up this did not occur. As activities can potentially positively influence an individual's mood and engagement score, this may account for the decrease in ME scores for this site.

For these reasons it is important to think about the scores obtained during Dementia Care Mapping in context rather than in isolation.

## **Strengths and Limitations**

### **Strengths**

#### ***Recruitment***

The study recruited more participants than was originally planned. Although initially it was feared that recruitment of people living with dementia might be low due to many people not being able to complete the self-report measures, introducing the use of proxy report measures ensured that a high proportion of people at each site could be included in the study. Research assistants strove to recruit as many people as possible at each site and the only reasons all people at each site were not recruited were; lack of consent, not available during the data collection period, did not have a dementia diagnosis and time pressures on staff to complete proxy measures (see Figure 5). It was considered important that as many people as possible at each site were given the opportunity to be involved in the study. Similarly, given that it was not known until analysis whether there would be significant differences between proxy and self-report scores on the QOL-AD so obtaining as many of each category of questionnaire was important. It was felt that the development of good working relationships at each site between the research assistants and the staff at the unit contributed considerably to the high recruitment figures. Reflection in the Trial Steering Committee and in research team meetings focused on the importance of the research assistants having had previous experience working in dementia care settings in allowing the development of a trusting working relationship with staff at the care homes that was built on mutual respect and understanding.

#### ***Study Design***

The study involved a rigorous investigation of the intervention which allowed for clear claims about its effectiveness and utility to be made. Without a rigorous framework for evaluation and a clear conceptual framework (outline in Figure 1) claims about effectiveness could have been made without giving consideration to the impact on wellbeing of the people living with dementia. It would have been possible to say that training improved knowledge and

attitudes, changed decision making strategies and, without considering a control group improved care plans. Without looking at the elements of care and wellbeing it could have been concluded that the intervention was a success. Considering the translation to improvements in care and wellbeing is not always considered in such approaches <sup>[103]</sup>.

### ***PPI Involvement***

There were high levels of engagement with people living with dementia and carers in all aspects of the study through the PPI work and their contributions both guided the study and influenced its direction. In total 79 different people either living with dementia or carers gave input into some element of the study design, delivery or the subsequent public engagement work. The involvement of people living with dementia and those who support them was felt to be of paramount importance in this study due to its congruence with the underlying principles of a Human Rights Based Approach to care. PPI is concerned with a shift to developing and carrying out research and development with or by members of the public and service users rather than on or for them simply as participants <sup>[104]</sup>. This helps to uphold and promote the Rights of each person to have ‘a right to voice’, with suppression or denial of that voice being a potential violation of Rights <sup>[105]</sup>. Similarly, the nature of this study and the fact that it was funded by NIHR makes this of even more importance as it could be considered a core democratic principle that ‘people who are affected by research have a right to have a say in what and how publicly funded research is undertaken’ <sup>[106,107]</sup>.

Alzheimer’s Europe recently issued a position paper <sup>[108]</sup> (reference) regarding involving people with dementia in research through PPI. In this paper they recommend that people living with dementia are involved in all aspects of research including the initial generation of research ideas. An important output from this study is the development of a PPI reference comprising of people living with dementia and carers who have developed an interest in promoting the area of Human Rights in dementia. Whilst their initial role was to support the current study they felt that it was of upmost importance that an output was accessible information which increased public awareness about the Human Rights of people living with dementia and how easily they can be undermined within society. This PPI reference group

will extend beyond the end of this study and will form the basis for the development of further research in the area.

### ***Innovative Methods***

Innovative methods were used throughout to try and ensure that information was elicited in ways that would be as ecologically valid as possible. It has previously been discussed within this report that every effort was made to include people living with later stages of dementia in the development of the assessment tool <sup>[69]</sup>.

A key element of the study was the exploration of staff decision making strategies. In order to assess this area staff were provided with clinical vignettes which were designed specifically for this study and combined potential Human Rights violations with person centred principles. Vignettes have long been used to investigate a number of phenomena in the social, behavioural, and health sciences <sup>[109]</sup>. Staff were read a number of clinical vignettes and asked what they would do in each particular situation. On each occasion they were asked supplementary questions of; ‘How would you come to that decision?’ and ‘What would help you in coming to that decision?’ It was felt that asking staff to reflect directly on their own experiences and how they make decisions may feel threatening to many people. Similarly, it is often unethical or impossible to assess clinical decision-making experimentally with real clinicians and service users in health care settings. So whilst vignette designs may be an alternative method for investigating how health clinicians make decisions that affect service user care it has been questioned whether a written stimulus, and a participant’s responses to it, can accurately represent certain aspects of what happens in the real world. It has been suggested that three conceptually distinct but functionally interrelated factors contribute to validity <sup>[110]</sup>.

1. Vignette must simulate aspects of real-world scenarios and bear some resemblance to situations encountered by the participant (construct validity).
2. Vignettes, and the differences between vignettes, elicit some kind of effect that is hypothesised to exist independently in the real world (internal validity – the degree

to which changes in the dependent variable can be accurately attributed to changes in the independent variable).

3. Vignette studies should produce results that generalise to real-world situations encountered by the participants and others like them (external validity).

It is important to note that vignettes are not intended to re-create real world situations.

Rather, they are designed to 'approximate, isolate, manipulate, and measure key aspects of the decision-making processes that individuals use in real world situations' <sup>[109, 111,112]</sup>.

Similarly, participants' behaviour in a vignette study is not intended to be interpreted as representative of their behaviour in the real world, but rather as strong predictors or proxies for such behaviour <sup>[111,112]</sup>. It is therefore more useful to think about whether the mental and behavioural processes used in responding to the vignettes are activated in a way similar to the manner that these processes are used in real life.

In considering these factors, the vignettes used in this study were developed collaboratively with staff working in dementia care setting in order to ensure that they accurately reflected clinical situations that they may encounter on a regular basis. They were refined during the pilot phase of the study. The vignettes elicited a wide range of distinct responses reflecting a variety of decision making strategies. It cannot be claimed however that the responses reflected proxies to behaviour as little, or no, behavioural change was noted as a result of the intervention despite decision making strategies changing.

### ***National Dementia Initiatives***

The approach was also congruent with a number of national initiatives related to dementia. There is a clear commitment to reducing the prescription of antipsychotic medication to people with dementia <sup>[88]</sup>. The principles of a Human Rights Based Approach, particularly proportionality, least restrictive practice and proactive strategies together with a detailed understanding of the person with dementia, through a person centred care plan, are key in finding alternatives to antipsychotic prescribing in challenging behaviour. A key to managing challenging behaviour is the understanding of the need being expressed through this behaviour <sup>[113]</sup>. An in depth knowledge of the person is obviously essential in helping

formulate this. It was proposed that the application of this approach would lead to more detailed person centred care plans that allow a more detailed knowledge of the person.

A NICE <sup>[47]</sup> quality standard for dementia is: “People with dementia have an assessment and an ongoing personalised care plan, agreed across health and social care, that identifies a named care coordinator and addresses their individual needs.” The proposed intervention, if applied, clearly addressed this issue.

Many of the concepts covered in the Getting it Right assessment map directly onto the standards of the Accreditation for Inpatient Mental Health Services (AIMS) process and therefore allow wards to meet the required the standards more readily. It was therefore hoped that the approach may be acceptable to sites as it would help them meet other requirements.

## **Limitations**

### ***Effectiveness and acceptability of the intervention***

Despite staff and managers stating that they found the approach useful and simple to use; *‘It was explained simply in layman’s terms’*, there was limited uptake of the approach in practice. It was hard to get staff to attend the booster sessions and releasing staff for training seemed extremely difficult. Whilst NHS wards were harder to recruit they did, once recruited have clear mechanisms in place which enabled staff to attend the training day. In contrast care homes were relatively easier to recruit but were often unable to protect the time for people to attend the training. There were multiple occasions when the trainer would attend a care home to find that no staff had been given dedicated time to attend and staff were taken off active duty to attend the training resulting in additional pressure on the other staff to cover their work. The fact that 2 out of 10 intervention sites were unable to undertake the training within the required time frame, despite prior knowledge of requirements demonstrates the difficulties or willingness sites had in releasing staff for training and development. Similarly, there were several staff from care homes who reported attending the training on their days off as they were interested in the topic but were not given the time within working hours to attend. Whilst this shows a positive commitment

from the individual staff it calls into question the commitment of those care homes to the approach.

Although it was initially envisaged that as many staff as possible would be trained at each site in reality only 8.88 (28.7%) staff at each site were recruited to the training. There was a wide range in the percentage of staff trained at each site; between 11.6% and 52.4%. Similarly the protocol suggested three 'booster sessions', which were designed to support the implementation of a Human Rights Based Approach, should be delivered to each site. In reality this was not possible. There is obviously a major difference between training the majority of staff at each sites and facilitating booster sessions to embed the approach (the expectation) and training an average of 28.7% of the staff with minimal follow-up (the reality). Staff who had attending training however were positive about the training, felt that it was tailored to meet their needs and impacted on their ability to complete their job successfully; *'The tutor lady was fab. Simple'*. Given the reluctance of sites to engage in training and booster sessions it is interesting that a theme from interviews with the intervention sites was that they would have liked more training, training for more staff and more booster sessions.

There was also evidence that the 'Getting it Right' assessment tool was not routinely completed at participating sites. When it was used, however, it was considered to be helpful; *'the training and the hand outs and the paperwork that they gave us has definitely helped'* and it had a positive impact on the work people were carrying out. Unfortunately there was no mechanism within the study to specify the number of assessments that needed to be completed at each unit and in hindsight this may have improved the completion rate.

These somewhat mixed findings about the acceptability and effectiveness of the intervention seem to reflect the finding that uptake varied across sites and that a number of factors influenced uptake. It was clear however that the majority of staff enjoyed the training and felt it was targeted at an appropriate level for their skills and knowledge. They also valued the 'Getting it Right' assessment tool but a variety of factors meant they were not always able to use it in their setting.

Ultimately, despite positive reports from staff about the approach there was also evidence that there was; difficulty engaging teams with the training, problems getting staff to attend

follow up sessions, limited use of the assessment tool and no impact on the care and well-being of people living with dementia. It could therefore not be concluded to be an effective intervention. This will be considered when offering training to the control sites (in line with the original protocol) and different models will be considered.

A further limitation of the study related to the intervention was the lack of any fidelity assessment. No attempts were made to assess with residents whether they found the application of the 'Getting it Right' assessment tool useful. The study may have been improved by adding this into the evaluation framework.

On reflection the evaluation mechanism used to assess the effectiveness of the intervention was completed with a population once removed from the direct intervention. Whilst it was staff who received the Human Rights training, completed the assessment tool and attended the booster sessions the primary outcome measure (QOL-AD) was completed with the residents at each unit. The team still maintain that it was of upmost importance that the wellbeing of people living with dementia, who were of course the recipients of the care from staff who had received the intervention, was assessed. Without improvements to the care and wellbeing of people living with dementia there is little use of applying the intervention. As discussed above however it may have been more useful to consider other ways of measuring the impact of the intervention on people living with dementia.

### ***Treatment as usual***

There was considerable variation in the baseline treatment and care at each individual site. Different sites adopted different models of care and completed different documentation which formed the basis of the care plan. There was no way to standardise the baseline care provided across the sites. In addition and as previously discussed, there was on occasion, external events that may have impacted on the recorded standard of care at different time points. For example one site had an orchestra visiting during baseline data collection which will have increased the wellbeing scores of residents and may therefore have skewed the baseline results.



Whilst the randomised controlled trial is widely considered the gold standard for evaluating new interventions some questions have been raised about its efficacy in dementia studies. It is recognised that promoting change in people living with dementia is very difficult and as a result many interventions targeting behavioural or psychological change are found to be ineffective in RCTs <sup>[114]</sup> even when qualitative evidence related to the same intervention is overwhelmingly positive <sup>[60]</sup>. If we add high levels of variation of treatment as usual to the picture then these issues will be compounded further. There is perhaps a need to seek alternative ways of effectively and rigorously evaluating the impact of interventions targeting the wellbeing of people living with dementia.

### ***Measurement of Cognitive Abilities***

There were difficulties with the completion of the ADAS-Cog resulting in fewer people than expected being able to complete the measure. As a result there was no conclusive way to ensure that the severity of dementia was comparable between hospital wards and care homes.

The ADAS-Cog is generally recommended as a useful tool to assess cognitive functioning in dementia trials <sup>[65]</sup> and it is especially useful for determining the extent of cognitive decline which can help to evaluate which stage of Alzheimer's disease a person is experiencing. Similarly, the ADAS-Cog is often used in clinical trials because it can determine incremental improvements or declines in cognitive functioning. Despite this it is a time consuming assessment to complete (up to 45 minutes per person) and in reality the majority of participants refused to complete the assessment. On reflection the use of a briefer screening assessment such as the Mini Mental State Examination or Addenbrooks Cognitive Examination may have yielded most useful results. Although they are less detailed than the ADAS-Cog there is a greater chance that people would have engaged with them and therefore some level of comparison could have been made.

### ***Blinding***

Despite intending to keep research assistants who were collecting the data blinded this did not occur at 7 out of the 20 sites. It is acknowledged that this could have biased the data collection but given the results, which suggest that there was no difference in care and wellbeing it perhaps becomes less important. It is also important to note that since staff acted as proxies for service users where no care was available (the majority of cases) staff who had attended the training were also unblinded and this may have influenced their response of the follow-up questionnaires.

### ***High Staff Turnover***

There were high levels of staff and management turnaround at several of the intervention sites, as demonstrated by table 34 below. Additionally at follow up 4 of the 8 intervention sites who had completed training had new managers. The table also demonstrated that at a number of sites staff had not been replaced meaning that the remaining staff members were under additional pressure. Conversely, at some sites there were additional new staff at follow-up meaning that the staff team was larger than at baseline. Obviously none of these staff will have been trained in a Human Rights approach and will therefore have reduced the percentage of staff trained in the approach at these sites. These factors are likely to have had implications for the continuation of the intervention at each site. Given that on average less than 30% of staff at each site were trained high staff turnover will make it even less likely that a critical mass of staff will be present to implement the intervention.

It is estimated that over 40% of care home staff leave their job within a year of taking up post and 60% within two years <sup>[115]</sup>. Crucially for those in care, the level of staff turnover can be a matter of life or death <sup>[116]</sup>. The Care Quality Commission (CQC) have noted a statistical link between those care homes with increased rates of staff turnover and notifications of death and have suggested that “too many changes in staff may result in gaps in care”<sup>[117]</sup>. It has been proposed that high levels of staff turnover make it impossible to adhere to the principles of continuity of care which are highlighted by NICE as being of upmost importance <sup>[116]</sup>.

**Table 34:** Staff Turnover

<b>Site</b>	<b>Total number of staff who left before follow up</b>	<b>Total Number of new staff at follow up</b>
<b>Dale Park</b>	7	7
<b>Redholme</b>	8	3
<b>Abbottsburry</b>	8	2
<b>Finch Manor</b>	0	2
<b>Avalon</b>	4	2
<b>Acacia Court</b>	2	2
<b>Irwell Ward</b>	5	8
<b>Meadowbank Ward</b>	4	2
<b>Tudorbank</b>	5	8
<b>Greenacres</b>	2	2
<b>Cherry Ward</b>	4	7
<b>Whiston &amp; Halton Wards</b>	1	3
<b>Leigh Ward</b>	3	2
<b>Hollins Park</b>	2	0
<b>Larkhill Hall</b>	9	8
<b>Cressington Court</b>	7	5
<b>Macclesfield</b>	0	2
<b>The Harbour</b>	0	4
<b>Thomas Leigh</b>	2	1
<b>St Luke's</b>	3	3

### ***Recruiting Carers***

There were major problems with recruiting informal carers to the study. It was initially anticipated that where possible a carer would be recruited for each participant. This goal was not achieved by a long way. The research assistants reported that many residents had no visitors at all and when people did have visitors the visitors were reluctant to complete measures. It has been estimated that 85% of care home residents have no visitors <sup>[118]</sup>.

Whilst this figure may be an over estimation in reality, it does suggest that there is a shift in the relationship of carer and person cared for when the care recipient enters a care setting. The term 'couplehood' is used to refer to the shared identity and experiences a couple have that help to reinforce their sense of themselves as a couple <sup>[119]</sup>. It could be hypothesised that the transition from living together at home to living apart with one half of the couple in a care setting may impact on couplehood as there may be reduced opportunities for new shared experiences. This could usefully be explored in further research.

Given that the difficulty recruiting carers is commonly reported in dementia studies this raises questions as to the most appropriate way to engage carers in research.

### ***Use of Proxy Measures***

Due to participants with dementia finding completion of the self-report version of the QOL-AD difficult it was necessary to also seek proxy completion of the measure. As in previous studies significantly lower scores were found from proxy report than from self-report. As a result it was necessary to analyse data from the proxy and self-report measures separately resulting in lower numbers for each group than would have been possible had the group been able to be analysed as a whole. The issues related to the use of proxy measures are described in detail above.

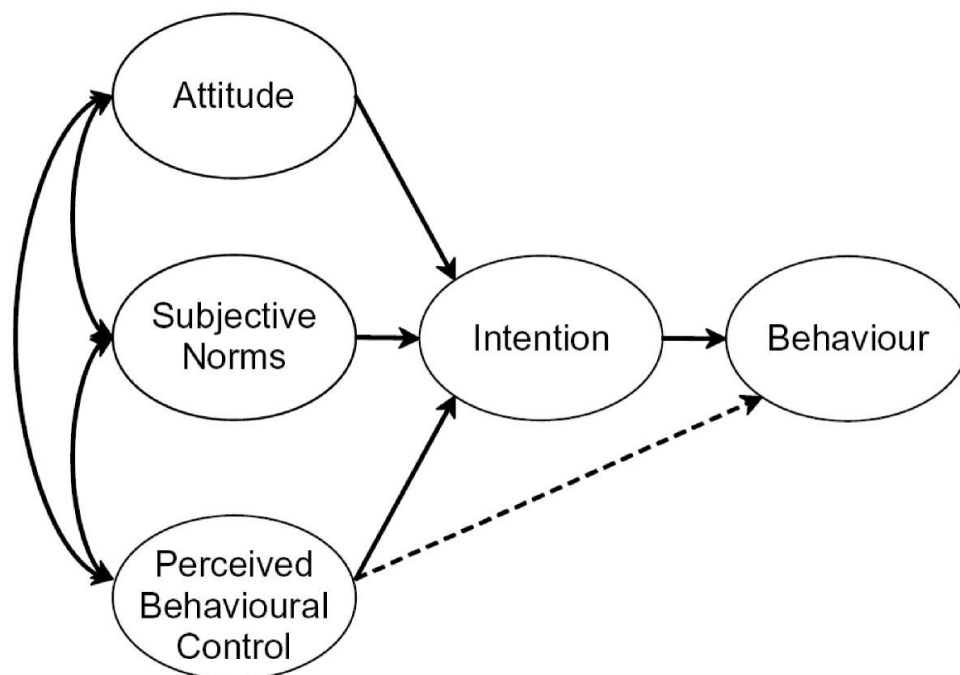
The issue of proxy completion was compounded by there being a lack visitors and this necessitating staff to complete proxy measures for residents.

## Interpretation

### Theory of Planned Behaviour

A major finding of the study is that whilst the intervention has changed the knowledge staff have about Human Rights, the attitudes that they hold and their reasoning about decision making in relation to clinical care it has not altered their behaviour when delivering care. The theory of planned behaviour <sup>[120]</sup> may hold some insights into this finding. The theory of planned behaviour proposes that the chances of an individual behaving in a particular way is influenced by their attitude towards the topic, how they perceive other people's (their peers) attitudes to the issue and their perceived level of control over the situation.

**Figure 8:** Theory of Planned Behaviour



Whilst the current intervention may change an individual's attitude towards Human Rights (as demonstrated by significant changes in the Attitudes Questionnaire) and their intention to behave in a way more congruent with a Human Rights Based Approach (as evidenced by improvements in care plans and different decision making strategies) the actual behaviour as measured by dementia care mapping remained unchanged. The theory of planned

behaviour would suggest that this discrepancy between actual and intended behaviour may be accounted for by considering staff's perceived level of control and perception of other's views about Human rights. Although the current study did not directly collect information on these areas some tentative conclusions could be drawn from the available data.

Whilst the initial intention was to train as many staff as possible in a Human Rights Based Approach practicalities meant that an average of less than 30% of staff at each site were trained in the approach. Similarly, there was limited uptake of booster sessions which would have provided staff, both trained and untrained in the approach, with the opportunity to discuss the application of a Human Rights Based Approach to care. As a result there may have been less opportunities for staff members to assess their peer's attitude to and understanding of a Human Rights Based Approach. This is further backed up by information from the follow-up interviews from intervention sites in which staff suggested that more opportunities to discuss with other staff at the unit the approach may have been helpful in applying it.

It has been hypothesised that perceived control relies on two elements; locus of control and self-efficacy. Whilst locus of control refers to a person's beliefs around whether or not people in general can achieve positive outcomes and avoid bad through their own actions or whether external factors control these outcomes, self-efficacy refers to the perception that a person themselves has the skills and abilities to enact effective responses. A common theme across all groups derived from the staff decision making interviews was the use of hierarchical decision making as a way of making clinical decisions. This implies a lack of control in making autonomous clinical decisions and instead a reliance on seeking consent prior to making any decisions, which may in turn lead to staff feeling that they are lacking self-efficacy to bring about change. Similarly, follow-up interviews at intervention sites highlighted that at units where managers encouraged staff to be independent thinkers and adopted a more transformational approach to leadership staff applied the model more effectively.

Given that a key finding of many care home studies is a lack of uptake of new interventions future research could usefully explicitly use the theory of planned behaviour to investigate Human Rights Based Approaches and their application.

## Management Style

Results from the follow-up interviews demonstrated the importance of management style in maximising the chances that this intervention would be adopted at any particular site.

Whilst there is insufficient evidence to make wide ranging claims about this element of the study initial findings showed that sites which had a more transformational manager were more likely to adopt the approach and think of ways to adapt it whilst sites with a more transactional manager were less likely to adopt the approach and to dismiss its relevance <sup>[85]</sup>.

It is maybe not completely surprising that management style has such an impact on uptake given that one of the most popular decision making strategies was hierarchical decision making. If management are not supportive and other staff are looking to them in relation to decision making then the approach will not be adopted.

An issue highlighted within the current study was that there was high turnover of managers at the units. At the follow up interviews half of the sites where the intervention had been delivered had new managers and there was evidence of poor communication between past and current management; *'I only heard about the study from this evaluation'*. It has been suggested that; *'In all the dementia care homes that really provide a new culture in dementia care this rests with a manager who knows how to lead rather than just manage'* <sup>[121]</sup> and that emotional intelligence is the key to good quality care <sup>[122]</sup>. A Joseph Rowntree report <sup>[123]</sup> exploring ways of improving the quality of care in care homes highlighted management as a key driver in developing and implementing improvements in the quality of care. They proposed that a change culture must start with managers who are willing to embrace change (in this study the transformational managers) and that these managers must empower staff to participate in decision making both about clinical care and the more organisational aspects of the unit. This fits well with the finding that staff felt reluctant to make decisions independently and instead sought advice from more senior colleagues. Linking to the theory of planned behaviour it would appear that managers would be key in enabling staff to feel that they have behavioural control over any new initiatives and facilitating their ability to implement it independently. This maximises the changes of new initiatives actually being implemented.

Given these findings it would seem vitally important that managers with the correct skills and the ability to develop effective teams are recruited to these important positions. There has been a move within the NHS and other services to utilise values based recruitment <sup>[124]</sup>. Values based recruitment aims to select candidates for roles based on their individual values and behaviours and how closely these align to the values of the organisation. It may be that selecting managers based on their values, particularly related to an ethos of person centred care may improve the care provided at a unit.

### **Cultures of Care**

Culture has been defined as ‘the basic assumptions, values and norms shared by and influencing how members of an organisation behave and interact’ <sup>[125]</sup>. Too often substandard care is accepted and unquestioned. It is expected that quality of life will be low in care homes and little else is aimed for. This can lead to care which is task orientated and driven by goals and objective rather than by resident orientated factors <sup>[123]</sup>. It is notoriously difficult to change cultures of care and whilst many initiatives are introduced there continues to exist a culture of care which falls short of the optimal standards.

It is unacceptable that the culture of care in care homes remains substandard and unable to meet the basic needs of the people that it cares for. A recent UNISON report <sup>[126]</sup> found that less than 20% of care home staff who responded to their questionnaire felt that they had enough time to provide care which upheld the dignity and individuality of residents. This led to residents not receiving treatment such as assistance to go to the toilet, efficient monitoring of their condition and personal care needs not being met. Shockingly 88% of workers reported not having time to have a conversation with their residents.

A large scale study looking at what constitutes an excellent culture in care homes (Care Home Organisations Implementing Cultures for Excellence – CHOICE <sup>[127]</sup>) identified seven factors which contribute to a positive culture in care homes:

1. Shared purpose in providing the best person centred care
2. A sense of community between all involved in the care home



3. Managers ensure external pressures do not have a negative impact on service delivery
4. Staff are empowered to take responsibility for resident wellbeing by active management processes
5. Openness to change for the benefit of residents
6. Using the care home environment to the benefits of residents
7. Person centred activity and engagement is integral to care work

These factors again mirror the findings of this report in that they highlight the importance of cementing person centred practice in care, not just talking about it, the centrality of management in ensuring that staff are empowered to take responsibility for their own practice and are protected from external pressures which may adversely impact on their ability to provide the best quality care and the necessity of cohesion amongst staff and managers in developing a positive culture at the unit.

This study aimed to utilise a Human Rights Based Approach to bring about cultural change. Previous work by the Equality and Human Rights Commission found that public authorities continued to lack a culture of respect for human rights, despite some examples of good practice<sup>[127]</sup>. They identified a numbers of barriers which they suggested could contribute to this finding. These included 'initiative overload'<sup>[128]</sup> with staff feeling that here is always something new to implement, a lack of autonomy amongst staff, the hierarchical and target-driven nature of healthcare settings<sup>[129]</sup>, and low awareness of Human Rights amongst staff, service users and members of the public. It has been suggested that the use of Human Rights language in conversations with organisations, staff and members of the public is ineffective due to this lack of awareness<sup>[130]</sup>. In contrast to this belief the current study demonstrated that training could raise awareness of Human Rights, improve attitudes towards Human Rights and, in the context of decision making, change staff's use of language about Human Rights.

The Care Quality Commission has integrated the FREDA principles into the inspection framework. When rights are fully integrated into policy and practice within services, the impact has been anecdotally described as 'a magnet pulling services in the direction that best supports the dignity, respect, equality and autonomy of those that use them'<sup>[127]</sup>. This

study does not endorse this finding. Instead it suggests that although a Human Rights Based intervention can change knowledge, attitudes and decision making it does not influence care delivery.

## **Training**

The findings of this study call into question the efficacy of training as a medium for improving care and changing culture. Although the training appears to significantly increase knowledge about Human Rights and positive attitudes towards Human Rights immediately following the training it does not translate into improved care practices and reported well-being of people living with dementia.

There is a current government mandate through Health Education England (HEE) to provide effective, relevant dementia education and training for the entire workforce <sup>[131]</sup>. However, it is recognised that there is limited evidence about what effective dementia training and education for this diverse workforce looks like <sup>[132]</sup>.

It seems important to consider what any training programme is aiming to achieve.

Kirkpatrick's model for the evaluation of learning <sup>[133]</sup> identifies 4 levels for evaluating the efficacy of training:

Level 1 – Reaction: Learners reaction to and satisfaction with the programme

Level 2 – Learning: The extent to which learning has occurred included increasing knowledge, skills, confidence and attitude change.

Level 3 – Behaviour: The extent to which staff behaviour or practice have changed and whether participants are applying their learning in practice.

Level 4 – results: examines what results have occurred because of the training, in this case the impact on people living with dementia

The remit in this study was to train staff in a Human Rights Based Approach with the aim of assisting staff in decision making in complex clinical situations. It also trained people in a new way of care planning and provided them with a tool to complete more person centred assessments. What it didn't do explicitly was teach people the skills to *behave* in a more person centred way. Given that there are low levels of knowledge of more basic issues related to dementia observed could we have expected people to make this transition independently? There was low uptake of the booster sessions but even if there were a higher uptake the sessions would not have been detailed enough to fulfil this role. In order to start meeting these goals we would be looking at a far more intensive model of coaching and consultation, there are examples of this such as the Newcastle model of challenging behaviour<sup>[134]</sup> but they are far more time and labour intensive and are therefore likely to also have financial consequences.

Preliminary results from the 'What works in dementia training programme'<sup>[131]</sup> suggest that there are a number of elements which contribute to training to bring about changes to people living with dementia. These are:

- Uses face-to-face delivery, discussion and activities that support application of learning to practice
- Is delivered by an experienced trainer
- Is over 1 hour in duration
- Is designed for a specific service setting type
- Provides training on a structured tool or delivery manual that assists application of learning in practice

This study utilised all aspects of this framework but failed to embed the approach into care. Given the results from this study it would be useful to add that it also requires support from management to both attend the training but more importantly to apply the approach to clinical situations.

## Patient and Public Involvement

A key element of the study has been the involvement of people living with dementia and those who support them. Not only was this congruent with the theoretical underpinning of the study by promoting participation and accountability, it was also essential in gaining a meaningful understanding of what Human Rights means to this group of people in the context of living with dementia. Much work has been undertaken over recent years to build Rights based approaches into policy <sup>[23,26,27,29,31,32]</sup> but this work has focused less on the practical application of these approaches to the everyday lives of people living with dementia. Without this focus there is a danger that Human Rights Based Approaches will suffer the same fate as person centred care where 'the gap between the rhetoric and the reality remains uncomfortably wide' <sup>[135]</sup>.

From the outset the PPI reference group felt it was essential to engage with the realities of applying a Human Rights Based Approach in dementia care. A series of focus groups involving both people living with dementia and carers were held throughout the duration of the study with the aim of eliciting information about the relevance of Human Rights when living with dementia. In total 79 different people attended these groups. Some of these people continued as part of the PPI reference group whilst others attended just one, or more focus group. Some focus groups were linked to other existing networks such as the local memory group and service user forum in order to hear from a wider range of voices than might otherwise have been accessed. No existing Human Rights models were presented to the groups and instead they were asked to reflect on, and explore elements of their experiences which have a positive and negative impact on their sense of wellbeing as individuals living with dementia.

This information was collated and a thematic analysis <sup>[80]</sup> undertaken to identify themes within the wide data set. These themes were then shared with the PPI reference group and translated into statements directly relevant to dementia care which reflect the Rights of people living with dementia. These statements are presented in Table 35. Subsequently Human Rights informed models were considered and the group felt that the statements fitted most comfortably into the FREDA (Fairness, Respect, Equality, Dignity and Autonomy)

framework. A notable exception raised in all the focus groups was the importance of preserving identity in dementia. This theme highlighted the importance of preserving elements of identity in the face of changing abilities. It is recognised that whilst dementia can pose a threat to an individual's sense of identity there is clear evidence of the persistence of self-identity throughout the course of the condition <sup>[136]</sup>. A social constructionalist model of self-identity <sup>[137]</sup> would posit that the interactions between the person living with dementia and other individuals are key in upholding the self-identity of the person living with dementia. If we view Human Rights as concepts which are universal to us purely through us being human then an argument for actively promoting identity in dementia as a fundamental right could be made. To this end we included identity in the FREDA framework when considering dementia.

**Table 35:** Mapping of dementia care onto FREDA Principles

FREIDA Principle	Statement
Fairness	Don't make assumptions about me Give me time and space Don't exclude me because of my dementia
Respect	Listen to me Find out who's important to me Make a positive effort to get to know me Speak to me Look at me when you speak to me
Identity	Respect my intelligence Recognise my skills and talents Respect my choices about how I want to live my life

	Let me live my life
Equality	Give me input into the care I receive Respect my culture, race and religion I have the right to intimate relationships I have the right to vote
Dignity	Don't embarrass me Ask my opinion Don't patronise me If you are helping me explain what you are doing to me
Autonomy	Allow me to express my views Respect my personal freedom Give me the freedom to do what I want which may include taking risks Provide assistance to make decisions for myself Take my significant others into account Give me advice but don't try to control me

It was felt that these statements linked to an already well recognised and respected Human Rights framework made a good start in defining what Human Rights mean to those living with dementia on a day to day basis. The FREDA principles have usefully been applied in other health care settings, including with people living with an intellectual disability (add reference). Defining the issues related to the systematic and subtle ways in which Human rights can be threatening in dementia care is of course a useful endeavour but if this information is not shared in a way that is accessible to many people it will not influence the treatment that people receive. The PPI group are currently working with filmmakers to

produce a short film which will represent these principles and their interpretation in an engaging way.

### ***Language***

It was considered important that all language used in this report was in line with the underlying principles of the study, upholding the Human Rights of people living with dementia. To this end every effort was made to adherence to language guidance outline by the Dementia Engagement and Empowerment Project (DEEP) which was compiled by people living with dementia <sup>[138]</sup>.

### **Implications for Health Care**

The findings of this study have a number of implications for both the current provision of health care and future developments.

There is a tendency within health and social care to utilise training as a primary mechanism for bringing about sustained change within care settings. Current initiative such as the requirement for all staff working in health care to have a basic level of dementia awareness <sup>[139]</sup> are, in theory, clearly beneficial to the population and aims to promote *'positive outcomes for people living with dementia, their families and carers'*. In practice, however, these training initiatives are often delivered through online training with little opportunity for discussion or debate around the issues raised and the extent to which they actually impact on the lives of service users and carers is unclear. Health Education England states that it exists for one reason only; *'to support the delivery of excellent healthcare and health improvement to the patients and public of England by ensuring that the workforce of today and tomorrow has the right numbers, skills, values and behaviours, at the right time and in the right place'* <sup>[140]</sup>. Whilst training is one vehicle to bring about such changes the findings of this study imply that whilst training may increase knowledge and attitudes about a topic and may even change the way people discuss the topic and intend to act there is little change to actual behaviours.

Many models of learning suggest that simply imparting information is not enough to bring about cultural and organisational change. Bloom's taxonomy <sup>[141]</sup> outlines stages of learning which culminate in all stakeholders creating a better culture together. This requires more than direct learning and instead requires that the learners are active participants in the process first remembering the information, then understanding it and critically analysing it before being supported to apply it and then synthesising it with their current knowledge and practice to create new cultures within organisations. This process is obviously more complex, time consuming and costly than providing an online or one day training package and expecting staff to utilise it.

One finding from this study was that whilst staff members found the approach to be useful and simple they did not independently apply it. The theory of planned behaviour applied to this situation would suggest that further opportunities for discussion of the topic and staff feeling empowered to make independent decisions may improve the chances of this initiative being adopted. These findings could potentially be useful beyond the confines of this study as they would suggest that if training is to be embedded in practice there will need to be opportunities for staff to consult and debate the issues involved in it and a freedom for them to act independently in ways that are congruent with the approach. Obviously this requires a shift in the methods in which training is delivered and the follow up support required.

The Kings Fund <sup>[142]</sup> suggests that a major reform of the health and social care system is required to make them fit for purpose for the future. They identify three challenges to innovative change in NHS systems. These are; system inertia where systems are stuck doing things in ways that they have always done them, the complexity of NHS systems where interactions cannot always be predicted and risk adversity within the NHS. All three of these barriers were encountered in the current study and have been discussed. They claim that, as in social enterprises, the answer comes in part from engaging with staff at all levels to empower them to make changes to their organisation. Related to this is seeking to build a social movement for change in which innovation occurs by harnessing the creativity, energy and commitment of the workforce. These suggestions are in line with a Human Rights Based



Approach to care which recognises the participation of all stakeholders and aims to empower these stakeholders.

A Human Rights based approach would also include people living with dementia and their carers as important stakeholders in this process. The inclusion in this study of a wider reference group of people living with dementia and carers has highlighted the importance of their involvement in all aspects of service delivery. There can be multiple benefits to service engaging with their service users and carers. The Dementia Engagement and Empowerment Project (DEEP) has produced guidelines about 'Making an Impact Together' <sup>[143]</sup>. This encourages people with dementia to work together to ensure that they receive quality services but also outlines the benefits to services. Service user groups often have a lot more freedom in relation to highlighting areas where change is needed and in pushing for this change to happen.

One clear finding was that care plans in both the intervention and control group improved at follow up data collection. This could be interpreted as suggesting that it is the process of being monitored which leads to improvements. There has long been a tension related to Human Rights between clinicians who feel that the most effective way to encourage staff to engage with Human Rights is through supporting them in applying them and Human Rights advocacy bodies e.g. the British Institute of Human Rights who propose that they are a legal framework people should be monitored against <sup>[34]</sup>. This finding would seem to suggest that the latter is more effective in this case and it might imply that setting clear standards for services related to Human Rights which they are then monitored against may be the most effective way to bring about change.

In order to bring about innovative change within systems however effective management and leadership will be of vital importance. It was observed in this study that when managers were more open to change and willing to let their staff act in a more independent way there was greater uptake of the approach. The issue of values based recruitment in order to ensure that managers who are willing to foster cultures where change can take place is discussed above. The findings would suggest that any new approaches should target management in the first instance to help ascertain what would work in their unit. This is the approach that will be adopted with the control sites that are still to receive training.

Whilst this study concluded that *this* Human Rights Based intervention was not effective in bringing about behavioural changes which resulted in improved care and wellbeing of people living with dementia it does not of course imply that the Human Rights of people living with dementia are not important. As outlined above barriers to Human Rights approaches being adopted have been noted including a lack of awareness of Human Rights and reluctance to engage with the concept. This study clearly demonstrated that staff will engage with the concepts of Human Rights and identify them as useful in the work they do. Addressing cultural issues described above may pave the way for a more explicitly Human Rights Based Approach to be adopted.

A final point relates to the current systems of measurement and data capture in health services. Whilst it is acknowledged that outcome measures are essential in ensuring that high quality services are being delivered the current study, and previous high profile studies<sup>[60]</sup> call into question the effectiveness of the current measures in capturing a true reflection of wellbeing and quality of life for those living with dementia. Services may wish to spend more time focusing on what elements of a person's life they feel the specific interventions will actually have an impact on and then finding ways to capture that data effectively.

## **Future Research Implications**

Some areas for future research and investigation arise from this study.

As discussed in detail above there were concerns about the suitability of the outcome measures used in this study. The utility of the QOL-AD as an appropriate scale to measure change following the implementation of this intervention was questioned and a review of the concepts contained in it suggested that many interventions currently delivered would not be likely to make a change. Given that there is a clear, and welcomed, mandate to further develop research that explores the most effective ways to promote well-being and deliver high quality care it will be vital that effective measurement tools are available that will accurately capture change. This study would suggest that this should be a research priority. Without appropriate measures there will continue to be a lack of clarity over the most appropriate ways in which to support people living with dementia, particularly those at

later stages of dementia. Related to this issue however, there appears to be a lack of research focused on fully understanding what contributes to quality of life at later stages of dementia and many assumptions are made about this. In order to develop meaningful evaluation tools it will first be vital to fully understand the factors that contribute to quality of life at later stages of dementia.

It was clear from this study that engaging carers in research was extremely difficult. More work must be carried out to ensure that carers are given every opportunity to engage with research and to have their voices heard. The PPI reference group suggested that people living with dementia and other carers may be good advocates for helping carers see the benefits of research both for themselves and for those they care for.

There is a need to understand more fully why interventions which are reported qualitatively as being effective and acceptable to services are not routinely applied. Two further focuses for research can be drawn from this:

1. Explicitly applying the theory of planned behaviour to Human Rights Based Approaches to look whether altering a person's perceived control over the situation improves the uptake of the intervention.
2. Working directly with managers to understand the impact management style has on the application of a Human Rights Based Approach (and other novel approaches to care).

At the outset this study worked from the premise that the Human Rights of people living with dementia would be the same as everyone else due to the nature of Human Rights being fundamental principles which apply simply because we are human beings. Public engagement throughout the course of the study however highlighted that the understanding of Rights when dementia is involved may be subtly different. One area that consistently arose was the centrality of identity in preserving and promoting the rights of people living with dementia. Similarly, there were numerous fascinating debates in the sessions related to the changing nature of autonomy and the relative importance, or not of individual autonomy as a concept. These are both areas which could warrant further research to investigate their role in quality of life and well-being of people living with dementia.

The IDEA questionnaire was developed as a way of trying to capture the extent to which people living with dementia felt their Human Rights were being upheld. It was developed collaboratively with people living with dementia, staff and carer but all the people living with dementia were at earlier stages of the condition. Within the study it was found not to be an effective tool as it tended towards a floor effect which the majority of people stating no violations of their rights. It was also too complex for people at later stages of dementia to effectively complete. More work is needed to ascertain whether this tool would be effective with people at earlier stages of dementia. It is also essential that work is undertaken to find ways to capture the extent to which people at later stages of dementia feel their Human Rights are upheld.

## **Conclusions**

The findings of this study did not support the hypothesis that increasing staff knowledge and attitudes towards Human Rights led to improvements in the care and wellbeing of people living with dementia. It does not of course imply that the issues of Human Rights are not important for this group of people. People at later stages of dementia remain some of the most vulnerable in our society and unfortunately reports of Human Rights abuses continue. There remains a need to find a way to ensure that the Human Rights of people with dementia are both respected and promoted.

The study highlighted some of the difficulties that exist within health and social care systems. The care and support that people received was inconsistent and failed to meet the standards we might expect for some of the most vulnerable in our society. Person-centred care was not routine and there were many examples of institutionalised behaviours. Human Rights were concepts that were alien to staff and were not routinely considered when providing care. Staff did not feel empowered to act independently to support the people at their units and the management support that was provided was variable. In order to provide

quality care that is person centred and respectful of the Rights of people with dementia it is essential that the cultures care is delivered in are suitable. The results of this study taken together give some indications of factors that may influence the development of these cultures of care. These include:

- Managers who lead and are willing to adopt an innovative approach to change
- All staff feeling empowered to make decisions and to act in ways that they see as appropriate.
- A shift away from training that has awareness raising as its only aim
- A tolerance of risk
- Full involvement of service users in service development and delivery
- Entire sites adopting new cultures
- Monitor progress in relation to Human Rights based targets

These factors link well with the PANEL principles which form the basis for a Human Rights Based Approach to care. They encourage active *participation* of all stakeholders including managers, staff and service users. They highlight the importance of all levels of staff being *accountable* for their own actions as opposed to always deferring to more senior colleagues. They actively promote the voices of vulnerable groups, in this case people living with dementia, in ensuring practices are *non-discriminatory*. They seek to *empower* all staff regardless of grade and to empower service users to take control of their own services and they provide a clear framework through adherence to Human Rights principle to ensure that all decisions taken are *legal*.

Overall, the study was hopeful in identifying that the majority of staff caring for people living with dementia were keen to explore how a Human Rights Based Approach to care could improve the lives of people living with dementia. In reality however these same individuals worked in cultures and organisations which did not explicitly promote person-centred care and the promotion of Human Rights. It is the challenge of those in positions of relative power to ensure that meaningful change is made which will allow the enthusiasm of care staff to translate into more effective and compassionate caring relationships with those they support.

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## Contributions of Authors

**Peter Kinderman** (Professor of Clinical Psychology) acted as principal investigator (PI) on the study, and led the team in study design, grant application and management, recruitment. He shared responsibilities with Sarah Butchard for supervision of research assistants, and other members of the team in data collection, interpretation of findings and drafting of the final report.

**Sarah Butchard** (Clinical Psychologist) conceived, planned and designed the study. She acted as the trial manager and coordinated the running of the study, delivered the intervention, interpreted qualitative elements of the study and led on the writing of the final report.

**Ashley Bruen** (Research Assistant) completed data collection, interpretation of Dementia Care Mapping findings and drafted elements of the final report.

**Abbie Wall** (Research Assistant) completed data collection, interpretation of Dementia Care Mapping findings and drafted elements of the final report.

**Nia Goulden** (Trial statistician), developed the statistical analysis plan, undertook the statistical analysis, aided interpretation of the results and drafted sections of the final report.

**Zoe Hoare** (Principle Statistician), gave input into the design and methodology of the study, designed the randomisation system, oversaw development of the statistical analysis plan and subsequent analysis, had input into the interpretation of the results and the presentation in the final report.

**Carys Jones** (Research Officer, Health Economics), design, analysis, interpretation of findings, writing and review of manuscript.

**Rhiannon Edwards** (Professor of Health Economics) Design, interpretation of findings, writing and review of manuscript.

**Data Sharing:** All available data can be obtained from the corresponding author once fully anonymised and checked.

This statement confirms that the report contains no defamatory material or brand names. The identity of all individuals have been protected throughout the report

## **Ethical Approval and Research Governance**

A protocol was submitted for ethical consideration to the National Research Ethics Service (NRES) committee North West – Haydock (ref: 14/NW/1117) in June 2014 and it was approved in August 2014. For participating NHS sites approval was also sought from the relevant NHS Trust research and development (R&D) departments.

## **Registration**

The trial was registered with the International Standard Randomised Controlled Trial Register (ISRCTN) under the reference number ISRCTN94553028

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## Appendices

### Appendix 1 – Getting it Right Assessment Tool

## **Appendix 2 – Outcome measures**

## **Appendix 3 – Supplementary tables**

# Appendix 1 – Getting it Right Assessment Tool

Mersey Care **NHS**  
NHS Trust

## Getting it right

### A Human Rights Based Assessment

with people with dementia

Name

Mersey Care NHS Trust  
8 Princes Parade  
Princes Dock  
St Nicholas Place  
Liverpool  
L3 1DL  
[www.merseycare.nhs.uk](http://www.merseycare.nhs.uk)

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## Getting it right



My name is



I like to be known as



Named nurse

This information helps to promote Respect and Equality

## Introduction

This booklet records your answers to some questions the staff have asked you to help them to get to know you better as a person. It helps them know how best to support you while you are staying here. It also informs you what will be happening and ensures that you have the best quality of life and receive high standards of care.

It is your right to be treated with fairness, respect and equality, in other words without discrimination. You will be supported to maintain dignity and have as much autonomy (capacity for independent choice) as possible. If you feel any of these principles are not being respected you should speak to a member of the staff team.

These are the FREDA Principles

- FAIRNESS** We will treat you fairly.
- RESPECT** We will treat you with respect.
- EQUALITY** We will treat you with equality, there will be no discrimination.
- DIGNITY** We will respect your dignity and do our best to ensure it is protected.
- AUTONOMY** We will respect your freedom of choice. As far as we can.

The coloured boxes in this booklet will be completed by your assessor over the course of your stay. They have been coded as follows.

- Stage 1 - This will be completed within the first 24 hours of your admission.
- Stage 2 - This will be completed within 3 days of your admission.
- Stage 3 - This will be completed within one week of your admission.

Human Rights  
to Healthcare

Liverpool

## Communication

Hearing



Comments

What will happen now?

Communication





Vision





This information helps to promote Respect and Equality

## Being here

Why am I here?



Comments

What will happen now?

How am I feeling?





Where to find information about me





Concerns about home





This information helps to promote Dignity and Autonomy

## Being here

Moving around



Comments

What will happen now?

Drinking





Eating



stage 1



stage 2



stage 3



This information helps to promote Equality, Dignity and Autonomy

## Personal care

Physical health



Comments

What will happen now?

Using the toilet





Getting washed and dressed





Sleep





Appearance





This information helps to promote Dignity and Autonomy

## My beliefs

My beliefs



Comments

What will happen now?

## Making decisions

Decision making



What helps

What will happen

Power of attorney- Yes/ No

Advanced directive- Yes/ No

This information promotes Equality

## Wellbeing and feelings

Decision making



What makes me feel better



What makes me feel worse



What will happen

This information promotes Equality

## Being on the ward

## Relationships

Environment



Comments

What will happen now?

Belongings



Doing



This information helps to promote Respect, Dignity and Autonomy

Important people to me



What will happen now?

Staying in touch



Sexuality



This information promotes Equality



Completed by:

Designation:

Date:



Completed by:

Designation:

Date:



Completed by:

Designation:

Date:

My signature

Carer's signature

## Appendix 2 – Outcome Measures

### QOL-AD

***I want to ask you some questions about your quality of life and how you would rate different aspects of your life using one of four words: poor, fair, good, or excellent.***

1. How do you feel about your physical health? Would you say it's poor, fair, good, or excellent? Circle whichever word you think best describes your physical health right now.

Poor	Fair	Good	Excellent
1	2	3	4

2. How do you feel about your energy level? Would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

3. How has your mood been lately? Have your spirits been good, or have you been feeling down? Would you rate your mood as poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

4. How about your living situation? How do you feel about the place you live now? Would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

5. How about your memory? Would you say it is poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

6. How about your family and your relationship with family members? Would you describe it as poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

7. How do you feel about your marriage? How is your relationship with (spouse's name)? Do you feel it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

8. How would you describe your current relationship with your friends? Would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

9. How do you feel about yourself—when you think of your whole self, and all the different things about you, would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

10. How do you feel about your ability to do things like chores around the house or other things you need to do? Would you say it's poor, fair, good or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

11. How about your ability to do things for fun that you enjoy? Would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

12. How do you feel about your current situation with money, your financial situation? Do you feel it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

13. How would you describe your life as a whole? When you think about your life as a whole, everything together, how do you feel about your life? Would you say it's poor, fair, good or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

ASCOT

***I would now like to ask you some questions about your daily life. Please circle one answer.***

1. Do you feel you have control over your daily life? By 'control over daily life' we mean having the choice to do things or have things done for you as you like and when you want.

No needs (Has control over daily life)	Some needs (Has some control over daily life but not enough)	High needs (Has no control over daily life)	Not known [If not known, go to the next question]
--	--	---	---

2. Do you feel clean and presentable? (In general not just at the present moment.)

No needs (Feels clean and presentable)	Some needs (Feels less than adequately clean or presentable)	High needs (Not at all clean or presentable)	Not known [If not known, go to the next question]
--	--	--	---

3. Are you getting enough food and drink? Do you get them at times that suit you?

No needs (Gets all the food and drink they like when they want)	Some needs (Doesn't always get adequate or timely food and drink)	High needs (Doesn't always get adequate or time food and drink and there is a risk to their health)	Not known [If not known, go to the next question]
---	---	---	---

4. How safe do you feel? By feeling safe we mean feeling safe both inside and outside the home. This includes fear of other people, falling or getting hurt.

No needs (Feels as safe as they would like)	Some needs (Feels less than adequately safe)	High needs (Doesn't feel safe at all)	Not known [If not known, go to the next question]
---	--	---------------------------------------	---

5. Do you have as much social contact as you want with people you like?

No needs (Has as much social contact with people they like)	Some needs (Has some contact, but not enough)	High needs (Has little social contact and feels socially)	Not known [If not known, go to the next question]
---	---	---	---

as they want)		isolated)	
---------------	--	-----------	--

6. Do you do things you value and enjoy with your time? (This could include leisure activities, formal employment, unpaid work or caring for others.)

No needs (Able to spend time as they want, doing things they value and enjoy)	Some needs (Does some of the things they value and enjoy, but not enough)	High needs (Does not do anything they value and enjoy)	Not known [If not known, go to the next question]
---	---	--	---

7. Is it clean and comfortable here?

No needs (The care home and resident's room are as clean and comfortable as they want)	Some needs (The care home and resident's room are not quite clean or comfortable enough)	High needs (The care home and resident's room are not at all clean or comfortable)	Not known [If not known, go to the next question]
--	--	--	---

8. How does having help to do things make you think and feel about yourself?

No needs (Having help either has no impact or actively makes the person think or feel better about themselves)	Some needs (Having help sometimes undermines the way the person think or feels about themselves)	High needs (Having help completely undermines the way the person thinks or feels about themselves)	Not known [If not known, go to the next question]
--	--	--	---

9. How does the way you are helped and treated here make you think and feel about yourself?

No needs (The way help is provided either has no impact or actively makes the person think or feel better about)	Some needs (The way help is provided sometimes undermines the way the person thinks or feels about)	High needs (The way help is provided completely undermines the way the person thinks or feels about)	Not known
--	---	--	-----------

themselves)	themselves)	themselves)	
-------------	-------------	-------------	--



## EQ-5D-3L

***I would now like to ask you some questions about your health and how you're feeling today. By circling one of the answers in each group below, please indicate which statements best describe your own health state today.***

### 1. Mobility

I have no problems in walking about	I have some problems in walking about	I am confined to bed
1	2	3

### 2. Self- Care

I have no problems with self-care	I have some problems washing or dressing myself	I am unable to wash or dress myself
1	2	3

### 3. Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities	I have some problems with performing my usual activities	I am unable to perform my usual activities
1	2	3

### 4. Pain / Discomfort

I have no pain or discomfort	I have moderate pain or discomfort	I have extreme pain or discomfort
1	2	3

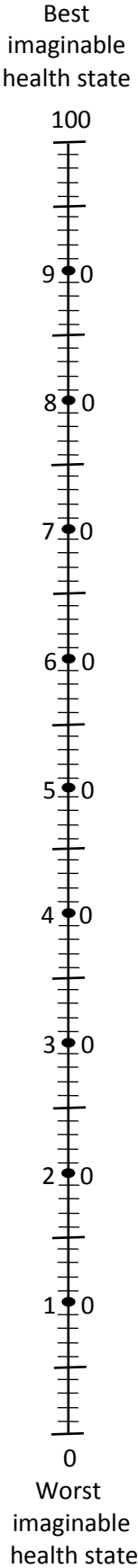
### 5. Anxiety / Depression

I am not anxious or depressed	I am moderately anxious or depressed	I am extremely anxious or depressed
1	2	3

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good/bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own  
health state  
today**



## CSRI

***How many times have you used the following services in the previous 4 months?***

### 1. Community Based Service Use

Service	Number of clinic visits	Number of home visits
Gp		
Practice Nurse		
Community/District Nurse		
Community Psychiatric/Mental Health Nurse		
Mental Health Team Worker		
Psychiatrist		
Psychologist		
Social Worker		
Care Manager		
Counsellor		
Dietician		
Optician		
Dentist		
Physiotherapist		
Occupational Therapist		
Alternative Therapist		
Other 1 (please specify)		
Other 2 (please specify)		
Other 3 (please specify)		
Other 4 (please specify)		
Other 5 (please specify)		

## 2. Hospital Based Service Use

Hospital Service	Reason for attendance	Number of attendances/nights
Accident and Emergency		
Assessment/Rehabilitation inpatient ward		
Continuing care/respice inpatient		
Day Hospital		
Other Inpatient Ward: admission 1		
Other Inpatient Ward: admission 2		
Other Inpatient Ward: admission 3		
Other Inpatient Ward: admission 4		
Outpatient ward: attendance 1		
Outpatient ward: attendance 2		
Outpatient ward: attendance 3		
Outpatient ward: attendance 4		
Other:		

### 3. Medication

***Please complete the table below to show medications that you have taken at any point during the previous 4 months?***

[illegible]

## IDEA

***Please think about the care you receive at/ from \_\_\_\_\_ and answer the following questions. Please choose only one answer for each question.***

1. Do people here treat you with dignity?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

2. Do people here treat you with respect?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

3. Do people here treat you as an individual?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

4. Do people here treat you as if you are important?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

5. Are you made to feel silly or stupid here?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

6. Do people here involve you in decisions about your care?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

7. Are you ignored here?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

8. Do people here talk down to you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

9. Do people look at you when they speak to you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

10. Do people here talk to you in a way that you can understand?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

11. Are your views ignored when decisions need to be made?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

12. Do people here show an interest in you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

13. Do people here take time to get to know you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

14. Do people here make assumptions about you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

15. Do people here help you make decisions for yourself?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

16. Are you able to choose how you spend your time?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

17. Do you have to do what you are told here?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

18. Do people here know who's important to you and respect this?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9



19. Are people you trust involved in decisions about your care when you need them to be?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

20. Do people here give you the time to do things?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

21. Do people here seem to understand your problems?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

22. Do people here take you seriously?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

23. If you get angry or upset do you think it will be held against you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

24. Are you treated fairly here?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

25. Do people here help you live as normal a life as possible?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

26. Do people here respect your choices in how you want to live your life?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

27. Do people treat you differently now?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

28. Are you supported to do lots of the things you used to do?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

29. Do you still have contact with the people who are important to you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

### Care Plan Audit

#### Instructions for use:

*Delete the appropriate response for each of the listed items to record if there is/is not evidence of the item in the care plan. Write any other comments in the space provided.*

**1. General Items**

**Please circle appropriate  
answer**

**Comments:**

Patient Identifier:

.....

Date of admission:

.....

Date of discharge:

.....

Existence of a care plan?	Yes No	
Type of documentation	Paper Electronic Both	
Named Signed Dated	Yes/No Yes/No Yes/No	
Care plan completed by (please only state profession)	_____	
Review date of care plan	Yes No	
End date of care plan (if applicable)	Yes No	
Diagnosis	Yes No	
Unexplained jargon/abbreviations	Yes No	If present how many occurrences:
Risk Assessment	Yes No	
Risk Management Plan	Yes No	
Goals Action Plan	Yes No	
Discharge Plan	Yes No	
Understanding of why they are on the ward/in the care home	Yes No	
Deprivation of Liberty Safeguards	Yes No	
Mental Capacity Act decisions	Yes No	

Mental Health Act Status	Yes No
Collaboration – mention of who was involved in creating the care plan	Yes No
If yes who was involved:	
Person with dementia	Yes/No
Relative/Family member	Yes/No
Professional	Yes/No
Other	Yes/No
Was the person with dementia asked if they wanted a copy	Yes No
Who else has copies:	
Person with dementia	Yes/No
Relative/Family member	Yes/No
Professional	Yes/No
Other	Yes/No
Person with dementia's preferred name recorded	Yes No
Preferred language recorded	Yes No
Any reference to Human Rights/FREDA	Yes No
Record any instances of Human Rights language:	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>

2. Physical Health	Yes/No	Comments:
Current health issues	Yes No	
List of treatments	Yes No	
Current weight/BMI – happy with this?	Yes No	
Smoking	Yes No	Amount per day:
Alcohol consumption	Yes No	Amount per day:
Blood pressure recorded	Yes No	
Do they wear glasses	Yes No	
Do they use a hearing aid	Yes No	
Special needs:  (Eating, drinking, communication, moving about, using the toilet, sleeping etc)	Yes No	
Pain	Yes No	Where:
Risk of falling	Yes No	
Other Comments:	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	

3. Mental Health	Yes/No	Comments:
Depressed feelings	Yes No	
(Any formal assessments e.g.		

Cornell Scale for Depression in Dementia)	
Anxious feelings  (Any formal assessments e.g. Beck Anxiety Inventory)	Yes No
Experience of other unpleasant feelings	Yes No
Particular symptoms relevant to individual's diagnosis	Yes No
Other Comments:          	

4. Cognitive Ability	Yes/No	Comments:
Visual processing problems	Yes No	
Ability to manage personal care	Yes No	
Memory issues	Yes No	
Communicating issues	Yes No	
Difficulties with planning/judging/controlling	Yes No	

5. Capacity for doing	Yes/No	Comments:
Predominant way of engaging with the world at the current time	Yes No	

Please circle person's level of ability:

**Eating/Drinking**

Automatic responses only

Requires assistance to begin task

Requires prompt to begin task

Goal directed action

A vertical line with four horizontal tick marks, one for each level of ability, used for rating the person's level of ability.

Please circle person's level of ability:

**Walking**

Automatic responses only

Requires assistance to begin task

Requires prompt to begin task

Goal directed action

A vertical line with four horizontal tick marks, one for each level of ability, used for rating the person's level of ability.

Please circle person's level of ability:

**Personal Care**

Automatic responses only

Requires assistance to begin task

A vertical line with three horizontal tick marks, one for each level of ability, used for rating the person's level of ability.



Requires prompt to begin task

Goal directed action

Please circle person's level of ability:

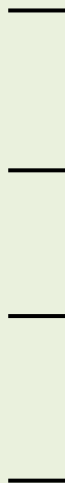
**Activities**

Automatic responses only

Requires assistance to begin task

Requires prompt to begin task

Goal directed action



6. Personal Preferences	Yes/No	Comments:
Food and drinks that the person likes	Yes No	

When and how the person likes to eat	Yes No	
Clothes the person likes to wear/how the person likes to look	Yes No	
Routines for Activities of Daily Living	Yes No	
Work-like activities that the person needs to do routinely	Yes No	

How the person relaxes	Yes No
People, places or objects that the person feels attached to/are important/want with them	Yes No
Spirituality	Yes No
Cultural beliefs	Yes No
Sexuality  (Orientation, sexual needs and preferences)	Yes No

7. Personality	Yes/No	Comments:
Comments or statements on personality dimensions	Yes No	

8. Life History	Yes/No	Comments:
<b>Early Years</b>		
Memories of family and friends	Yes No	
Memories of schooling and education  (Interests, friends, teachers, achievements)	Yes No	

Stories from early years	Yes No
<b>Middle Years</b>	
Memories of family and friends	Yes No
Memories of things the person did	Yes No

(Work, hobbies, holidays)	
Stories from middle years	Yes No
<b>After Retirement</b>	
Memories of family and friends	Yes No
Memories of things the person enjoyed	Yes No
(Hobbies, travel etc)	
Stories from after retirement	Yes No
<b>Now</b>	
Who and what I think about	Yes No
(People close to me, proudest achievements, regrets, happiest memories)	
Recent stories	Yes No
Activities/hobbies I enjoy	Yes No

9. Life at the moment	Yes/No	Comments:
Well-being/ill-being – how the person feels	Yes No	

Carer or significant other's satisfaction with the care (Any comments from carers)	Yes No
Person with dementia's satisfaction with the care (Any comments from person with dementia)	Yes No
Psychological needs (Comfort, occupation, attachment, identity, inclusion)	Yes No

10. Future Wishes	Yes/No	Comments:
Plans for inability to communicate wishes in the future  (Lifestyle preferences, treatments and support the person would/would not accept, list of people to consult regarding treatment and support decisions)	Yes No	
Mention of Advanced Directive or Living Will	Yes No	
Attorney's appointed  (For property, welfare, Lasting Power of Attorney)	Yes No	

### WEMWBS

***To begin with, we would like to ask some questions about you and how you are feeling at the moment. Below are some statements about feelings and thoughts. Please tick the box that best describes your experience of each over the last 2 weeks.***

1. I've been feeling optimistic about the future

None of the	Rarely	Some of the	Often	All of the time
-------------	--------	-------------	-------	-----------------

time		time		
1	2	3	4	5

2. I've been feeling useful

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

3. I've been feeling relaxed

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

4. I've been feeling interested in other people

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

5. I've had energy to spare

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

6. I've been dealing with problems well

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

7. I've been thinking clearly

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

8. I've been feeling good about myself

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

9. I've been feeling close to other people

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

10. I've been feeling confident

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

11. I've been able to make my own mind about things

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

12. I've been feeling loved

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

13. I've been interested in new things

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

14. I've been feeling cheerful

None of the time	Rarely	Some of the time	Often	All of the time
1	2	3	4	5

## ZBI

***Please circle the response that best describes how you feel. The term 'relative' will be used in relation to the person you support.***

1. Do you feel that your relative asks for more help than he or she needs?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

2. Do you feel that, because of the time you spend with your relative, you don't have enough time for yourself?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

3. Do you feel stressed between caring for your relative and trying to meet other responsibilities for your family or work?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

4. Do you feel embarrassed about your relative's behaviour?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

5. Do you feel angry when you are around your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4



6. Do you feel that your relative currently affects your relationships with other family members or friends in a negative way?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

7. Are you afraid about what the future holds for your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

8. Do you feel that your relative is dependent upon you?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

9. Do you feel strained when you are around your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

10. Do you feel that your health has suffered because of your involvement with your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

11. Do you feel that you don't have as much privacy as you would like, because of your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

12. Do you feel that your social life has suffered because you are caring for your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

13. Do you feel uncomfortable having your friends over because of your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

14. Do you feel that your relative seems to expect you to take care of him or her, as if you were the only one he or she could depend on?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

15. Do you feel that you don't have enough money to care for your relative, in addition to the rest of your expenses?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

16. Do you feel that you will be unable to take care of your relative much longer?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

17. Do you feel that you have lost control of your life since your relative's illness?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

18. Do you wish that you could just leave the care of your relative to someone else?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

19. Do you feel uncertain about what to do about your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

20. Do you feel that you should be doing more for your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

21. Do you feel that you could do a better job in caring for your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

22. Overall, how burdened do you feel in caring for your relative?

Never	Rarely	Sometimes	Quite Frequently	Nearly Always
0	1	2	3	4

**QOL-AD - proxy**

**Now we would like to ask you some questions about the person you support. *Please rate your relative's current situation, as you see it. Circle your responses.***

1. How do you feel about your relative's physical health? Would you say it poor, fair, good or excellent? Circle whichever word you think best describes your relative's physical health right now.

Poor	Fair	Good	Excellent
1	2	3	4

2. How do you feel about your relative's energy level?

Poor	Fair	Good	Excellent
1	2	3	4

3. How has your relative's mood been lately? Have their spirits been good, or have they been feeling down? Would you rate their mood as poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

4. How about your relative's living situation? Would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

5. How about your relative's memory? Would you say it is poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

6. How about you're relative's family and their relationship with family members? Would you describe it as poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

7. How do you feel about your relative's marriage? How is their relationship with (spouse's name)? Do you feel it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

8. How would you describe your relative's current relationship with their friends? Would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

9. How do you feel about your relative—when you think of their whole self, and all the different things about them, would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

10. How do you feel about your relative's ability to do things like chores around the house or other things they need to do? Would you say it's poor, fair, good or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

11. How about your relative's ability to do things for fun that they enjoy? Would you say it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

12. How do you feel about your relative's current situation with money, their financial situation? Do you feel it's poor, fair, good, or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

13. How would you describe your relative's life as a whole? When you think about their life as a whole, everything together, how do you feel about their life? Would you say it's poor, fair, good or excellent?

Poor	Fair	Good	Excellent
1	2	3	4

## ASCOT

***Please circle how you see your relative's daily life.***

1. Do you think your relative feels he/she has as much control as possible over their daily life?

<b><i>I think my relative feels he/she has...</i></b>			
As much control over daily life as they want	Some control over daily life but not enough	No control over daily life	Not known

2. Do you think the support and services from the care home/ward affect how much control your relative has over their daily life?

Yes	No
-----	----

**(If yes or don't know, then go to question 3. If no, then go to question 4)**

3. Imagine that your relative didn't have the support and services from the care home/ward that they do now and no other help stepped in. In that situation, which of the following do you think would best describe how your relative would feel?

<b><i>I think my relative would feel he/she has...</i></b>			
As much control over daily life as they want	Some control over daily life but not enough	No control over daily life	Not known



4. Thinking about keeping clean and presentable in appearance, which of the following statements best describes how you think your relative feels about their situation?

<i><b>I think my relative...</b></i>			
Always feels clean and presentable	Occasionally feels unwashed or not properly dressed	Does not feel at all clean or presentable	Not known <b>[If not known, go to question 7]</b>

5. Do you think the support and services that your relative gets from the care home/ ward affect their personal care, by which we mean being clean and presentable in appearance?

Yes	No
-----	----

**(If yes or don't know, then go to question 6. If no, then go to question 7)**

6. Imagine that your relative didn't have the support and services from the care home/ ward that they do now and no other help stepped in. Which of the following do you think would then best describe how your relative would feel?

<i><b>I think my relative would...</b></i>			
Feel clean and appropriately dressed	Feel occasionally unwashed or not properly dressed	Not feel at all clean or presentable	Not known <b>[If not known, go to question 7]</b>

7. Thinking about the food and drink your relative gets, which of the following statements best describes how you think your relative feels about their situation?

<i><b>I think my relative feels he/she...</b></i>			
Gets all the food and drink they like when they want	Doesn't always get adequate or timely food and drink	Doesn't always get adequate or timely food and drink, and	Not known

		there is a risk to their health	
--	--	---------------------------------	--

8. Do you think the support and services that your relative gets from the care home/ ward affect whether he/she gets the food and drink he/she wants or needs?

Yes	No
-----	----

**(If yes or don't know, then go to question 9. If no, then go to question 10)**

9. Imagine that your relative didn't have the support and services from the care home/ ward that they do now and no other help stepped in, which of the following do you think would then best describe how they would feel with regard to food and drink?

<b><i>I think my relative would feel that he/she...</i></b>			
Would get all the food and drink they like when they want	Wouldn't always get adequate or timely food and drink	Wouldn't always get adequate or timely food and drink, and there would be a risk to their health	Not known

10. Which of the following statements do you think best describes how safe your relative feels?

<b><i>I think my relative...</i></b>			
Feels as safe as they want	Feels less than adequately safe	Doesn't feel safe at all	Not known

11. Do you think the support and services that your relative get from the care home/ ward affect how safe he/she feels?

Yes	No
-----	----

**(If yes or don't know then go to question 12. If no then go to question 13)**

12. Imagine that your relative didn't have the support and services from the care home/ ward that he/she does now and no other help stepped in. In that situation, which of the following do you think would best describe how safe he/she would feel?

<b><i>I think my relative...</i></b>			
Would feel as safe as they want	Would feel less than adequately safe	Wouldn't feel at all safe	Not known

13. Thinking about how much contact your relative has with people they like, which of the following statements do you think best describes how he/she feels?

<b><i>I think my relative feels he/she has...</i></b>			
As much social contact with people they like	Some social contact but not enough	Little social contact with people and feels socially isolated	Not known <b>[If not known, go to question 16]</b>

14. Do you think the support and services that your relative gets from the care home/ ward affect how much contact he/she has with people he/she likes?

Yes	No
-----	----

**(If yes or don't know then go to question 15. If no then go to question 16)**

15. Imagine that your relative didn't have the support and services from the care home/ ward that they do now and no other help stepped in. In that situation, which of the following do you think would best describe how your relative would feel?

<i><b>I think my relative would feel that he/she has...</b></i>			
As much social contact as they would like	Some social contact but not enough	Little social contact and would be socially isolated	Not known

16. Thinking about how your relative spends his/her time, which of the following statements do you think best describes how he/she feels?

<i><b>I think my relative feels he/she...</b></i>			
Spends their time as they want, doing things they value or enjoy	Does some of the things they value and enjoy, but not enough	Doesn't do anything they value and enjoy with their time	Not known <b>[If not known, go to question 19]</b>

17. Do you think that the support and services that your relative gets from the care home/ ward affect how your relative spends their time?

Yes	No
-----	----

**(If yes or don't know then go to question 18. If no then go to question 19)**

18. Imagine that your relative didn't have the support and services from the care home/ ward that they do now and no other help stepped in. In that situation, which of the following do you think would best describe how your relative feels?

<b><i>I think my relative would feel that he/she...</i></b>			
Would be able to spend time as they want, doing things they value or enjoy	Would do some of the things they value and enjoy, but not enough	Would not do anything they value and enjoy with their time	Not known

19. Which of the following statements do you think best describes how clean and comfortable your relative feels the home or ward is?

<b><i>I think my relative feels that the home or ward and his/her own room...</i></b>			
Are as clean and comfortable as they want	Are less than adequately clean or comfortable	Are not at all clean or comfortable	Not known

20. Do you think the support and services that your relative gets from the care home/ ward affect how clean and comfortable the home is?

Yes	No
-----	----

**(If yes or don't know then go to question 21. If no then go to question 22)**

21. Imagine that your relative didn't have the support and services from the care home/ ward that they do now and no other help stepped in. In that situation, which of the following do you think would best describe how your relative would feel?

<b><i>I think my relative would feel that...</i></b>			
<p>           Their accommodation would be as clean and comfortable as they wanted         </p>	<p>           Their accommodation would be less than adequately clean or comfortable         </p>	<p>           Their accommodation would not be at all clean or comfortable         </p>	<p>Not known</p>

22. Which of these statements do you think best describes how your relative feels about having help to do things?

<b><i>I think my relative feels that...</i></b>			
<p>           Having help to do things either has no impact or makes them feel better about themselves         </p>	<p>           Having help to do things sometimes undermines the way they think and feel about themselves         </p>	<p>           Having help to do things completely undermines the way they think and feel about themselves         </p>	<p>Not known</p>

23. Which of these statements do you think best describes how your relative feels about the way they are helped and treated?

<b><i>I think my relative feels that...</i></b>			
<p>           The way they are helped and treated either has no impact or makes them feel better about themselves         </p>	<p>           The way they are helped and treated sometimes undermines the way they think and feel about themselves         </p>	<p>           The way they are helped and treated completely undermines the way they think and feel about themselves         </p>	<p>Not known</p>

### EQ-5D-3L

***We would now like to ask you some questions about your relative's health. By circling one of the answers in each group below, please indicate which statements your relative would choose to describe his/her health state today.***

#### 1. Mobility

I have no problems in walking about	I have some problems in walking about	I am confined to bed
1	2	3

#### 2. Self- Care

I have no problems with self-care	I have some problems washing or dressing myself	I am unable to wash or dress myself
1	2	3

#### 3. Usual Activities (e.g. work, study, housework, family or leisure activities)

I have no problems with performing my usual activities	I have some problems with performing my usual activities	I am unable to perform my usual activities
1	2	3

#### 4. Pain / Discomfort

I have no pain or discomfort	I have moderate pain or discomfort	I have extreme pain or discomfort
1	2	3

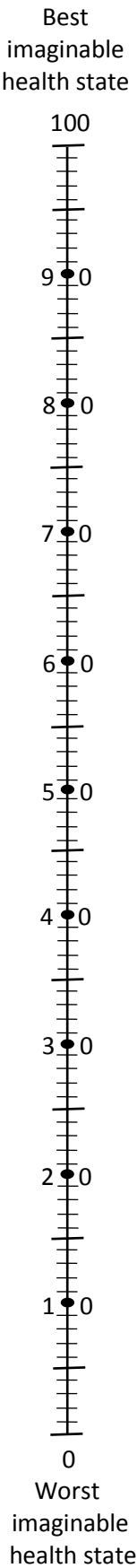
#### 5. Anxiety / Depression

I am not anxious or depressed	I am moderately anxious or depressed	I am extremely anxious or depressed
1	2	3

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good/bad your relative would say his/her health is today. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

**Your own  
health state  
today**





## IDEA

***Please think about the care your relative receives at the care home / ward and answer the following questions. Please choose only one answer for each question.***

1. Do people here treat (name) with dignity?

Yes	Sometimes	No
1	2	3

2. Do people here treat (name) with respect?

Yes	Sometimes	No
1	2	3

3. Do people here treat (name) as an individual?

Yes	Sometimes	No
1	2	3

4. Do people here treat (name) as if he/she is important?

Yes	Sometimes	No
1	2	3

5. Is (Name) made to feel silly or stupid here?

Yes	Sometimes	No
1	2	3

6. Do people here involve (name) in decisions about his/her care?

Yes	Sometimes	No
1	2	3

7. Is (Name) ignored here?

Yes	Sometimes	No
1	2	3

8. Do people here talk down to (name)?

Yes	Sometimes	No
1	2	3

9. Do people look at (name) when they speak to him/her?

Yes	Sometimes	No
1	2	3

10. Do people here talk to (name) in a way he/she can understand?

Yes	Sometimes	No
1	2	3

11. Are (Name's) views ignored when decisions need to be made?

Yes	Sometimes	No
1	2	3

12. Do people here show an interest in (name)?

Yes	Sometimes	No
1	2	3

13. Do people here take the time to get to know (name)?

Yes	Sometimes	No
1	2	3

14. Do people here make assumptions about (name)?

Yes	Sometimes	No
1	2	3

15. Do people here help (name) to make decisions for himself / herself?

Yes	Sometimes	No
1	2	3

16. Is (Name) able to choose how he/she spends their time?

Yes	Sometimes	No
1	2	3

17. Does (Name) have to do what he/she is told here?

Yes	Sometimes	No
1	2	3

18. Do people here know who's important to (name) and respect this?

Yes	Sometimes	No
1	2	3

19. Are people (name) trusts involved in decisions about his/her care when he/she needs them to be?

Yes	Sometimes	No
1	2	3

20. Do people here give (name) the time to do things?

Yes	Sometimes	No
1	2	3

21. Do people here seem to understand (name's) problems?

Yes	Sometimes	No
1	2	3

22. Do people here take (name) seriously?

Yes	Sometimes	No
1	2	3

23. If (name) gets angry or upset do you think it will be held against him/her?

Yes	Sometimes	No
1	2	3

24. Is (Name) treated fairly here?

Yes	Sometimes	No
1	2	3

25. Do people here help (name) live as normal a life as possible?

Yes	Sometimes	No
1	2	3

26. Do people here respect (name's) choices in how he/she wants to live his/her life?

Yes	Sometimes	No
1	2	3

27. Do people treat (name) differently now?

Yes	Sometimes	No
1	2	3

28. Is (Name) supported to do lots of the things he/she used to do?

Yes	Sometimes	No
1	2	3

29. Does (Name) still have contact with the people who are important to him/her?

Yes	Sometimes	No
1	2	3

## **Interview Schedule**

We are interested in asking you about how you make decisions in your day to day working life. There are no right or wrong answers and the information you give will not be shared with managers or supervisors. You are free to leave at any time. Do you have any questions?

Working within dementia care we are aware that you will regularly be in situations where you have to make complex clinical decisions about an individual's care. Could you tell us about some of the clinical situations that you find most challenging on a day to day basis?

I would now like to ask you about some specific situations you may encounter in your day to day working practice. Again there are no right or wrong answers we are just interested in your opinion.

### **Vignette 1**

What would you do?

How would you come to this decision?

What would help you or support you in making this decision?

### **Vignette 2**

What would you do?

How would you come to this decision?

What would help you or support you in making this decision?

### **Etc....**

That is all the clinical situations we would like to ask you about. Do you think that the situations we have asked about reflect your day to day work?

Thank you for participating in this study. We will make you aware of any results from the work. Do you have any questions you would like to ask?

## Vignettes set 1

### Life History

***Freedom of Expression*** – Anne is a married woman with a diagnosis of frontal temporal dementia. Since being admitted to the ward she has formed a close friendship with a male service user, John. John and Anne often sit together in the day room and have been seen holding hands and hugging each other. What would you do?

### Neurological Impairment

***Discrimination*** – Nadia has a diagnosis of Alzheimer's. Her son lives in Spain but has come over to visit her. 10 minutes before he is due to arrive you noticed that Nadia is soaked in urine. You encourage her to go for a wash and explain it is because her son is coming to visit. She refuses and does not seem to understand what you are telling her. What would you do?

### Personality

***Liberty*** – George has a diagnosis of Alzheimer's and has been on the ward for several weeks. His family report that he has always been an active man who has enjoyed the outdoors. It has been noticed that George spends long periods of time pacing around the ward. At times this irritates other service users. George can become tired after pacing and at times he has stumbled but never fallen. Because of this a member of staff needs to accompany him when he walking around the ward. What would you do?

### Health

***Degrading Treatment*** – Sheila was admitted to the dementia ward from the nursing home she lives in as they had noticed an increase in her levels of agitation. She recently had a fall whilst she was going to the toilet. Despite this she insists that she does not want someone to assist her and can go to the toilet on her own. What would you do?

### Social Psychology

***Peaceful enjoyment of possessions*** – Rajesh has always been interested in music and listening to it often calms him down. His family have brought him in a CD player and a selection of CDs. There has been an issue with another service user going into people's rooms and taking their personal possessions. Rajesh's family have asked whether his CDs will be safe. What would you do?

## Vignettes set 2

### Life History

**Discrimination** – Frank is an ex-boxer and despite his diagnosis of vascular dementia he is still extremely physically fit. It has been recorded that at times he has hit out at both staff and other service users on the ward. When this is discussed with his family at ward round they confide that he has a history of violence within the home and they do not want him to return home. What would you do?

### Neurological Impairment

**Liberty** – Desmond has been admitted to the dementia ward on an informal basis. He is often observed rattling the front door and asking to go out. His family question this. They are told that all service users who are on the ward on an informal basis are given the code to the door. His family state that because of his memory problems he would be unable to retain this information. What would you do?

### Personality

**Freedom of expression** – Ping is a 75 year old lady with a diagnosis of vascular dementia. She has been prescribed a variety of medications to help control multiple physical problems and also to help with her agitation. Every day at medication time Ping states that she has always been a fit and healthy woman and does not need to take any medication. She then refuses to take it. What would you do?

### Health

**Right to life** – Norman has a diagnosis of Alzheimer's but also suffers with an undiagnosed medical condition resulting in urinary retention. The urinary retention requires the insertion of a catheter at the local acute hospital and some further investigations to diagnose the condition. The family have asked that whilst Norman is on the dementia ward could the staff accompany him to these appointments. When staff have attended with him in the past he has become very agitated and distressed and one occasion slid out of his wheelchair onto the floor. What would you do?

### Social Psychology

**Private family life** – Joan has a diagnosis of Alzheimer's and has been becoming increasingly distressed on the ward. During the afternoon she becomes increasingly aggressive with both staff and other service users, eventually hitting another female service user. The decision is made to give Joan PRN medication and she then goes to sleep. When her family come to see her she has been asleep for about 30 minutes. What would you do?



## Attitudes Quiz

*Please circle your answer to the following questions.*

**1. I feel I understand the idea of human rights.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**2. Human rights are important for everyone.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**3. It is important to protect a person's human rights, regardless of who they are.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**4. The idea of human rights is something I do not consider important as part of my own values, attitudes and beliefs.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**5. The idea of human rights fits well with my understanding of the core values, aims and objectives of the NHS.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**6. Human rights are not useful or relevant to my day-to-day work.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**7. Human rights are about doing what is decent and fair.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**8. I feel that my own human rights are respected and I am treated well within my organisation.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**9. When people talk to me about human rights I feel pressured to work in a way I don't like.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**10. Positive change can happen at work using human rights values and approaches.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**11. Other people in my team at work do not have a strong belief in human rights.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

**12. My family and friends have a strong belief in human rights.**

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

## **Knowledge Quiz**

**Please circle one correct answer for each of the following questions**

### **1. Human rights:**

- a) Belong to certain groups at certain times
- b) Can be taken away from any of us
- c) Are claimed and cannot be taken away

### **2. In the United Kingdom who is protected by the Human Rights Act?**

- a) Everyone who works for a government organisation (e.g. nurses, teachers and civil servants)
- b) Everyone who has the right to vote
- c) Everyone regardless of status
- d) Everyone who is a UK citizen

### **3. In which of the following circumstances do the NHS and its staff have a responsibility to act in relation to human rights?**

- a) Preventing breaches of human rights; for example, intervening to protect one individual from the actions of another
- b) Informing individuals when their rights may be at risk - so they can make decisions to protect their own rights
- c) Responding to breaches of human rights, including investigating what has happened
- d) All of the above

### **4. The framework that gives the rights contained in the European Convention on Human Rights direct effect in UK law is:**

- a) The Bill of Rights
- b) The UK constitution
- c) The Human Rights Act

### **5. FREDA stands for:**

- a) Freedom, Respect, Equality, Diversity, Autonomy
- b) Fairness, Rights, Equality, Dignity, Autonomy
- c) Fairness, Respect, Equality, Dignity, Autonomy

### **6. Non– absolute rights can be interfered with if the action/decision is:**

- a) In pursuit of a legitimate aim
- b) Lawful
- c) Necessary

- d) Proportionate
- e) All of the above
- f) Only b and d

**7. Which one of the following rights is absolute?**

- a) The right to respect for private and family life, home and correspondence
- b) The right to be free from inhuman or degrading treatment
- c) The right to freedom of expression
- d) The right to manifest one's religion or belief.

**8. The right to respect for private life and family life, home and correspondence includes which of the following?**

- a) Physical wellbeing
- b) Psychological wellbeing
- c) The right to a house
- d) Not having your post intercepted
- e) a, b and d
- f) a, b and c

**9. When a person lacks the capacity to give informed consent to treatment Deprivation of Liberty Safeguards (DoLS) should be applied for:**

- a) Whenever something is to be done to an individual which is outside of usual working practice
- b) As part of best practice, as soon as someone is admitted to a ward environment
- c) Whenever something is to be done to an individual which deprives them of their liberty.

**10. Which of the following is not part of a human rights based approach:**

- a) Putting human rights at the heart of policy and planning
- b) Empowering staff & service users
- c) Ensuring clear accountability
- d) Non-discrimination and attention to vulnerable groups
- e) Ensuring you always do what the service user wants
- f) Enabling meaningful involvement and participation of all key people

**11. A proactive strategy is primarily a response that aims to minimise harm by acting:**

- a) Before an event
- b) During an event
- c) After an event

**12. Proportionality means the same as:**

- a) Using the least restrictive strategy
- b) Using common custom and practice
- c) Doing what the person and their family want

**13. Which of the following people's human rights might need to be taken into account when making decisions in a healthcare organisation?**

- a) Service users
- b) Carers
- c) Staff
- d) The wider community
- e) All of the above

## Appendix 3 – Supplementary Tables

List of job roles of the staff interviewed for the study:

Job Title	Control N (%)	Intervention N (%)
Acting Senior Carer		1 (0.8%)
Activities Co-ordinator	2 (1.6%)	
Activity Co-ordinator	2 (1.6%)	1 (0.8%)
Apprentice Clinical Support Worker		1 (0.8%)
Assistant Practitioner	2 (1.6%)	
Assistant Support Worker	1 (0.8%)	
Care Assistant	18 (14.5%)	27 (21.8%)
Care Assistant & Acting Senior		1 (0.8%)
Care Assistant/Driver		1 (0.8%)
Care Home Manager		1 (0.8%)
Care Worker	2 (1.6%)	2 (1.6%)
Carer	3 (2.4%)	6 (4.8%)
Clinical Lead		2 (1.6%)
Clinical Specialist	1 (0.8%)	
Physiotherapist		
Clinical Support Worker		19 (15.3%)
Deputy Manager	2 (1.6%)	
Deputy Ward Manager	1 (0.8%)	1 (0.8%)
Domestic		1 (0.8%)
Gardener/Domestic		1 (0.8%)
General Nurse	2 (1.6%)	
Health Care Assistant	42 (33.9%)	8 (6.5%)
Health Care Assistant - training to be Assistant Practitioner	1 (0.8%)	
Health Care Support Worker	1 (0.8%)	
House Keeper/Carer	1 (0.8%)	
Health Support Worker		1 (0.8%)
Hotel Services Manager		1 (0.8%)
Kitchen Assistant	1 (0.8%)	
Maintenance Lead		1 (0.8%)
Manager		1 (0.8%)
Mental Health Nurse	1 (0.8%)	
Nurse	6 (4.8%)	3 (2.4%)
Nurse Practitioner		2 (1.6%)
Nursing Assistant	2 (1.6%)	1 (0.8%)
Occupational Therapist		2 (1.6%)
Occupational Therapist Assistant	1 (0.8%)	1 (0.8%)
OT Assistant/Care Assistant	1 (0.8%)	
Physical Health Nurse	1 (0.8%)	
Physiotherapist	1 (0.8%)	
Physiotherapy Assistant	1 (0.8%)	
Portuguese		1 (0.8%)
Registered Manager	1 (0.8%)	

RMN	2 (1.6%)	1 (0.8%)
Senior Care Assistant	2 (1.6%)	6 (4.8%)
Senior Carer	4 (3.2%)	3 (2.4%)
Senior Health Care Assistant	1 (0.8%)	
Senior Unit Manager		1 (0.8%)
Staff Nurse	3 (2.4%)	4 (3.2%)
Supervised Practice Nurse	2 (1.6%)	
Supervised Practitioner Nurse	1 (0.8%)	
Supervisor		1 (0.8%)
Support Worker	8 (6.5%)	13 (10.5%)
Team Leader	2 (1.6%)	1 (0.8%)
Trainee Assistant Practitioner	1 (0.8%)	1 (0.8%)
Unit Manager		1 (0.8%)
Unit Manager/Nurse		1 (0.8%)
Ward Manager		2 (1.6%)
Total	124 (100.0%)	124 (100.0%)

Mean values for the two treatment groups at the two assessment points for ADAS-Cog:

Alzheimer's Disease Assessment Scale						
		N	Minimum	Maximum	Mean	Std. Deviation
GROUP 1	Pre	8	13.67	46.33	31.17	10.52
	Post	1	27.33	27.33	27.33	N/A
GROUP 2	Pre	5	16.33	44.33	29.53	11.97
	Post	0	N/A	N/A	N/A	N/A
TOTAL	Pre	13	13.67	46.33	30.54	10.63
	Post	1	27.33	27.33	27.33	N/A
DID NOT COMPLETE	Pre	319	N/A	N/A	N/A	N/A
	Post	435	N/A	N/A	N/A	N/A



Mean values for the two treatment groups at the two assessment points for IDEA Proxy:

		IDEA Proxy				
		N	Minimum	Maximum	Mean	Std. Deviation
GROUP 1	Pre	3	31.00	37.00	34.00	3.00
	Post	N/A	N/A	N/A	N/A	N/A
GROUP 2	Pre	2	29.00	33.14	31.07	2.93
	Post	2	36.00	41.00	38.50	3.54
TOTAL	Pre	5	29.00	37.00	32.83	3.04
	Post	2	36.00	41.00	38.50	3.54
DID NOT COMPLETE	Pre	318	N/A	N/A	N/A	N/A
	Post	421	N/A	N/A	N/A	N/A

Mean values for the two treatment groups at the two assessment points for WEMWBS:

		Warwick-Edinburgh Mental Well-being Scale				
		N	Minimum	Maximum	Mean	Std. Deviation
GROUP 1	Pre	3	41.00	47.00	44.00	3.00
	Post	0	N/A	N/A	N/A	N/A
GROUP 2	Pre	3	48.00	52.00	50.33	2.08
	Post	2	38.00	48.00	43.00	7.07
TOTAL	Pre	6	41.00	52.00	47.17	4.17
	Post	2	38.00	48.00	43.00	7.07
DID NOT COMPLETE	Pre	317	N/A	N/A	N/A	N/A
	Post	421	N/A	N/A	N/A	N/A

Mean values for the two treatment groups at the two assessment points for ZBI:

		Zarit Burden Interview (ZBI)				
		N	Minimum	Maximum	Mean	Std. Deviation
GROUP 1	Pre	3	28.00	37.00	33.03	4.59
	Post	0	N/A	N/A	N/A	N/A
GROUP 2	Pre	3	8.38	34.00	19.71	13.06
	Post	2	10.00	30.38	20.19	14.41
TOTAL	Pre	6	8.38	37.00	26.37	11.40
	Post	2	10.00	30.38	20.19	14.41
DID NOT COMPLETE	Pre	317	N/A	N/A	N/A	N/A
	Post	421	N/A	N/A	N/A	N/A

Outcome measures for all available participants at both time points:

	N	Min	Max	Mean	Std. Deviation
<b>T1 ASCOT TOT</b>	85	.22	1.0	.862	.138
<b>T2 ASCOT TOT</b>	70	.09	1.0	.848	.181
<b>T2 ASCOT PROXY TOT</b>	147	.16	1.0	.805	.173
<b>T2 ASCOT PROXY TOT</b>	176	.2	1.0	.809	.165
<b>T1 EQ-VAS</b>	71	50.0	100.0	78.23	16.766
<b>T2 EQ-VAS</b>	62	.0	100.0	74.19	24.23
<b>T1 EQ-VAS PROXY</b>	202	5.0	100.0	62.71	19.993
<b>T2 EQ-VAS PROXY</b>	236	10.0	100.0	60.53	19.57
<b>T1 EQ-5D TOT</b>	101	-.043	1.0	.743	.267
<b>T2 EQ-5D TOT</b>	86	-.077	1.0	.714	.284
<b>T1 EQ-5D PROXY TOT</b>	202	-.371	1.0	.354	.337
<b>T2 EQ-5D PROXY TOT</b>	233	-.536	1.0	.381	.339
<b>T1 QOL-AD TOTAL</b>	103	26.00	51.00	36.56	5.462
<b>T2 QOL-AD TOTAL</b>	93	22.75	45.00	35.33	5.57
<b>T1 QOL-AD PROXY TOT</b>	183	14.08	47.67	30.89	7.270
<b>T2 QOL-AD PROXY TOT</b>	224	13.00	46.09	31.69	6.72
<b>T1 WEMWBS TOTAL</b>	6	41.0	52.0	47.17	4.167
<b>T2 WEMWBS TOTAL</b>	2	38.0	48.0	43.00	7.07
<b>T1 ZBI TOTAL</b>	6	8.381	37.00	26.37	11.398
<b>T2 ZBI TOTAL</b>	2	10.00	30.38	20.19	14.41

Breakdown of the medications prescribed for 254 participants at baseline:

	Number
<b>Anaesthesia</b>	
General Anaesthesia	1
Local Anaesthesia	4
<b>Cardiovascular system</b>	
Anticoagulants And Protamine	22
Antiplatelet Drugs	83
Beta-Adrenoceptor Blocking Drugs	42
Diuretics	55
Hypertension and Heart Failure	42
Lipid-Regulating Drugs	78
Nit,Calc Block & Other Antianginal Drugs	42
Positive Inotropic Drugs	13
<b>Central nervous system</b>	
Analgesics	171
Antidepressant Drugs	147
Antiepileptics	30
Drugs for Dementia	113
Drugs Used In Nausea And Vertigo	9
Drugs Used In Parkinson's/Related Disorders	8
Drugs Used In Psychoses & Rel.Disorders	92
Drugs Used In Substance Dependence	2
Hypnotics And Anxiolytics	150
<b>Ear, nose and oropharynx</b>	
Drugs Acting On The Nose	1
Drugs Acting On The Oropharynx	1
Other Appliances	1
<b>Endocrine system</b>	
Corticosteroids (Endocrine)	12

Drugs Affecting Bone Metabolism	25
Drugs Used In Diabetes	34
Sex Hormones	3
Thyroid And Antithyroid Drugs	31
<b>Eye</b>	
Anti-Infective Eye Preparations	8
Miscellaneous Ophthalmic Preparations	6
Treatment Of Glaucoma	15
<b>Gastro-intestinal system</b>	
Acute Diarrhoea	4
Antisecretory Drugs+Mucosal Protectants	96
Antispasmod.&Other Drgs Alt.Gut Motility	5
Chronic Bowel Disorders	2
Dyspep&Gastro-Oesophageal Reflux Disease	6
Laxatives	184
<b>Infections</b>	
Antibacterial Drugs	23
Antifungal Drugs	2
Antiprotozoal Drugs	4
<b>Malignant disease and immunosuppression</b>	
Sex Hormones & Antag In Malig Disease	1
<b>Musculoskeletal and joint diseases</b>	
Drugs Used In Neuromuscular Disorders	5
Drugs Used In Rheumatic Diseases & Gout	11
Soft-Tissue Disorders & Topical Pain Rel	3
<b>Nutrition and blood</b>	
Anaemias + Other Blood Disorders	62
Base/Dil/Susp Agents/Stabilisers	3
Minerals	7